



Health Sciences Journal

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The HEALTH SCIENCES JOURNAL

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Article 1

A Randomized Controlled Clinical Trial on the Effect of Cooled Proparacaine Eyedrops on Ocular Pain upon Instillation among Normal Filipinos

Jocelyn Therese M. Remo, M.D.; Jonathan A. Rivera, M.D.; Edgar U. Leuenberger, M.D., DPBO, FPGS

Department of Ophthalmology

ABSTRACT

Introduction/Objective: The aim of this study was to determine the efficacy of cooled Proparacaine eyedrops in decreasing ocular pain for ophthalmologic procedures.

Methods: This was a double-blind, randomized controlled clinical trial involving 70 eyes of 70 male and female patients aged 20-40. These eyes were instilled with cooled Proparacaine eyedrops (Experimental group) or room-stored Proparacaine eyedrops (Control group). Five new bottles of Proparacaine eyedrops were stored in a refrigerator and five new bottles of Proparacaine eyedrops were stored at room temperature at least 24 hours before testing. One drop of cooled or room-temperature Proparacaine eyedrops was instilled to the right eye of each subject. The pain noted upon instillation was then graded by each subject using the VAS score and recorded. All scores were analyzed using the independent t-test. Baseline characteristics and demographics were compared using the chi-square test.

Results: The mean Visual Analogue Scale score of the Experimental group was 2.1714 and that of the Control group was 2.9714. The one-tailed p-value was 0.021614. There was a statistically significant decrease in the mean VAS for ocular pain in the Experimental group.

Conclusion: Cooled Proparacaine eyedrops decreased the ocular pain sensation among patients undergoing ophthalmic examinations.

KEY WORDS: Proparacaine, ocular pain

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential damage to tissues.¹ Pain in the eye may begin on the external layer or within its internal composition, the conjunctiva and the cornea. A sharp, burning or itching feeling may be experienced when pain is felt in the surface of the eye. This may be due to irritants or foreign body materials that are introduced onto the surface of the eye.²

Anatomically, the cornea is a transparent, avascular tissue with an aspheric shape that is very pain-sensitive. It has one of the body's highest densities of nerve endings, and its sensitivity is 100 times that of the conjunctiva. These sensory nerves extend from the long ciliary nerves and form a subepithelial plexus.² Proparacaine is one of the most commonly used agents for anesthesia and analgesia in the eyes. In the Philippines, Proparacaine is one of the leading ocular anesthetic agents used in ophthalmic screenings, examinations, and surgical procedures. However, two of its side effects are stinging sensation and burning pain.³ It is not unusual for patients to feel discomfort immediately after instillation of this eye drop. In pediatric patients, once the eye is instilled with Proparacaine eyedrops, the child immediately experiences discomfort and will not cooperate thereafter. Thus, this study was done to evaluate the effect of cooled Proparacaine eye drops on the ocular stinging sensation of normal eyes. To date, no work on the subject has been published, based on extensive literature search of electronic databases as well as the Philippine Journal of Ophthalmology archives.

Proparacaine is a topical anesthetic drug of the amino ester group. It is available as its hydrochloride salt in ophthalmic solutions at a concentration of 0.5%.⁵ The exact mechanism whereby Proparacaine and other local anesthetics influence the permeability of the cell membrane is unknown; however, several studies indicate that local anesthetics may limit sodium ion permeability through the lipid layer of the nerve cell membrane. Proparacaine appears to bind or antagonize the function of voltage gated sodium channels.⁴ It may alter epithelial sodium channels through interaction with channel protein residues. This limitation prevents the fundamental change necessary for the generation of the action potential.⁶

Earlier studies done abroad looked into the effect of temperature on topical anesthetics. A study entitled "The Effect of Temperature on the Discomfort Caused by Topical Local Anaesthesia"⁷ done in England in 1995 assessed the effect of temperature on the discomfort caused by the local anesthetic eye drops Amethocaine 1%, Oxybuprocaine 0.4% and Lignocaine 4%. Each patient group received a topical anesthetic at 42°C in one eye and at room temperature in the other. No statistically significant difference was found between the discomfort caused by drops at each temperature for any of the three anesthetics studied. There appeared no benefit in warming topical anesthetic agents prior to their use.⁶

A similar study was published in Iran in 2009 entitled "Cooling Tetracaine to Reduce Pain of Instillation before Surgery".⁷ The study aimed to evaluate the effect of cold Tetracaine drop on post-instillation ocular pain and burning sensation in patients undergoing phacoemulsification. Patients were randomly allocated into two groups of cold (case) and warm (control) Tetracaine eye drops. In the case group, the Tetracaine eyedrops were preserved in the refrigerator (4°C) whereas in another group, the drops were at room temperature (25°C). Their results showed that cooling Tetracaine reduced the pain on instillation of topical anesthesia in patients undergoing phacoemulsification.

The aim of this study was to determine the efficacy of cooled Proparacaine eyedrops in decreasing ocular pain in normal human volunteers.

METHODS

This was a phase 1 randomized controlled clinical trial conducted at the UERMMMC from August to September 2011 in normal human volunteers. The study protocol was approved by the UERM Scientific & Ethics Review Board.

Seventy (70) eyes of 70 subjects were included in the study. The subjects underwent complete ophthalmic examination including Schirmer's testing, intraocular pressure (IOP) determination via applanation tonometry, gonioscopy and fundus examination in the first week. The subjects were briefed and trained on how to use the pain-measuring device prior to the actual procedure. A blinded assistant was trained and briefed on the instillation technique and actual procedure of the study. Subjects were assigned to either of 2 groups using simple randomization generated from the computer software www.randomizer.org. Group A was the experimental group (Cooled Proparacaine), while Group B was the control group (Proparacaine at Room temperature).

Included in the study were males or females, aged 20-40 years. Excluded were subjects who had prior ophthalmic surgery, contact lens wearers, those being treated with analgesics or any eyedrops, diagnosed with dry eye, with history of addiction to opioids, history of hypersensitivity to anesthetics, noted infection and corneal abrasions, and abnormal tonometry and gonioscopy findings.

Five new bottles of Proparacaine eyedrops maintained at storage temperature of 2-8 degrees Celsius, and five new bottles of Proparacaine eyedrops maintained at room temperature (20-25 degrees Celsius) were used and labeled as A1, A2, A3, A4 and A5, respectively, for the Experimental group, and B1, B2, B3, B4, B5, respectively, for the Control group. These bottles were stored either in the refrigerator or inside the room at least 24 hours before the actual testing. Each bottle was used for one subject to minimize temperature alteration. One drop of Proparacaine eye drops was instilled into each subject's right eye at the optimal minimum time after storage. Proper instillation technique was followed.

The subjects were instructed to close their eyes for 30 seconds and were not allowed to squeeze their eyes. Subjects were then asked to mark on a visual analogue scale (VAS) line the intensity of the pain felt. The VAS pain scale was used, consisting of a continuous 10 cm line, with 0 for "no pain" and 10 for "worst possible pain". All adverse events were monitored throughout the course of the study.

The mean pain score of each group was computed and compared using the independent t-test at the 0.05 level of significance. The baseline demographics of subjects were compared using the chi square test and independent t-test: chi square for the nominal variables, and independent t-test for continuous variables. All data were encoded and analyzed using the SPSS v14.0 statistical software.

Assuming a mean VAS pain score difference of 3cm, at 0.05 level of significance and 90% power to detect a statistically significant difference, the calculated sample size was 35 subjects per group, for a total of 70 subjects.

RESULTS

A total of 70 eyes of 70 patients were included in this study. Thirty-five eyes were instilled with cooled Proparacaine eyedrops, and 35 eyes were instilled with Proparacaine eyedrops stored at room temperature. For the Experimental group (cooled Proparacaine), the youngest subject was a 22 year old female while the oldest was a 33 year old male. The mean age was 25.37 ± 2.46 years. Majority (94.28%) of the subjects were 21-30 years old. For the control group, 5 subjects were in the youngest age group at 23 years, 4 female and 1 male. The mean age was 25.86 ± 2.58 years. Majority (94.28%) of the subjects were 21-30 years. There was no significant difference in terms of the age and gender distribution ($p = 0.212$ and $p = 0.800$).

Table 1. The comparison of baseline demographics of the subjects included

Characteristic	Cooled Proparacaine		Room-Stored Proparacaine		p-value*
	N = 35	%	N = 35	%	
*Age (years)					0.211607 (NS)
21-30	33	94.28%	33	94.28%	
31-40	2	5.72%	2	5.72%	
Mean	25.37	2.46	25.86		
Standard Deviation			2.58		
**Sex					0.80000 (NS)
Male	10	28.57%	9	25.71%	
Female	25	71.43%	26	74.29%	
	35	100%	35	100%	

NS= not significant

*computed using the Chi-square test**computed using the independent t-test

As shown in Table 2 the mean pain score for the Experimental group (cooled Proparacaine) was 2.17 + 1.59 (range = 0-5), compared to 2.97 + 1.71 (range = 0-6) for the control. This difference was statistically significant ($p = 0.021614$, t-test).

Table 2. The computed mean pain score per group

	Cooled Proparacaine	Room Proparacaine	P value
Pain Score	2.17 +/- 1.59	2.97 +/- 1.71	0.021614
(VAS)	(Pain score range: 0-5)	(Pain score range: 0-6)	

VAS = Visual Analogue Scale

DISCUSSION

It is well known that the application of cold leads to an analgesic effect on the body part being treated. It has been demonstrated that nerve conduction decreases constantly with a decrease in temperature until conduction within the nerve fibers ceases completely. The myelinated fibers are the first ones to be affected. This slowing of the conductivity of the peripheral nerve fibers occurs when the temperature drops to below 27 degrees Celsius. Other mechanisms are also involved: cold has a specific anti-irritant function that protects from pain stimulus. Cold can also remove other causes of pain by reducing muscle spasm of the traumatized area, thus reducing the effects of ischemia secondary to the trauma.⁸

In this study, we observed that cooling Proparacaine eyedrops prior to instillation decreased the stinging effect and pain sensation. Similarly, the previous studies mentioned earlier also stated the fact that cooling significantly decreased the pain experienced by the subjects.^{7,8}

We also considered the time onset of anesthesia of Proparacaine. In the process of instillation, proper instillation technique was followed. The assistant/administrator of the eye drops was instructed on the proper way of instillation of eye drops. Each subject was asked to look up while tilting the head back. Simultaneously, the lower lid was pulled down and a drop of Proparacaine was instilled on the fornix. The subject was then asked to close his eyes lightly to avoid spillage of the eye drops. This was maintained for thirty seconds – the time it takes for anesthesia to begin.¹⁰

In summary, our study showed that cooled Proparacaine eyedrops decreased the ocular pain sensation among patients undergoing ophthalmic examinations. Prior to all ophthalmic examinations and procedures, it is advisable to store Proparacaine eyedrops in temperatures between two to eight degrees Centigrade to minimize or eliminate stinging sensation. Related studies as to test the effect of cooling Lidocaine in intracameral injection intra-operatively are also recommended.

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Article 2

A Randomized Controlled Trial on Acupuncture vs. Nicotine Replacement Therapy in Relieving Symptoms of Smoking Withdrawal

Ken Jeffrey O. Magcalas, Paolo C. Manalastas, Gia A. Mandigma, Jan Patrick C. Mangrobang
 Jenny Lyn D. Mangulabnan, Marielle Lois M. Manuel, Maria Luisa D. Maranan, Jenneth Crystal G. Marcha,
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 Mendoza, Jamie Leigh L. Mendoza, Vanessa P. Migallos, Brick Carlo L. Mirabueno, Grace E. Brizuela, MD, MSPH

Department of Preventive and Community Medicine

ABSTRACT

Introduction/Objectives: Smoking is a major cause of morbidity and mortality the world over and is implicated in a number of diseases such as peripheral arterial disease, emphysema, and ischemic heart disease. This study aimed to determine the effectiveness of acupuncture therapy compared with nicotine replacement therapy (NRT) in relieving symptoms of smoking withdrawal.

Methods: Twenty-two smokers aged 18-35 were randomized into two groups receiving either acupuncture therapy or NRT with nicotine patches. Withdrawal symptoms before and after intervention were measured through the Wisconsin Smoking Withdrawal Scale (WSWS).

Results: Paired *t*-test showed no significant difference between post-intervention mean withdrawal scores of the acupuncture group ($x = 86.00$, $SD = 7.707$) and NRT group ($x = 77.55$, $SD = 6.977$) with a *p*-value of 0.497. Before and after scores show a general decrease in withdrawal scores after the administration of the intervention.

Conclusion: Results of this study suggest that acupuncture therapy and NRT did not significantly lessen withdrawal symptoms. There was no significant difference between withdrawal symptoms of the acupuncture and NRT groups. However, there was a general decrease in individual withdrawal symptoms scores after the administration of both interventions. Moreover, acupuncture therapy significantly reduced anxiety and concentration.

KEYWORDS: smoking cessation, acupuncture therapy, nicotine replacement therapy, withdrawal symptoms

INTRODUCTION

Smoking is a major cause of morbidity and mortality worldwide. According to the World Health Organization (WHO), smoking is responsible for 90% of all lung cancer, 75% of chronic bronchitis and emphysema and 25% of all cases of ischemic heart disease.¹ In the Philippines, it is estimated that 60% of men smoke, 40% of which are adolescents. Given this, roughly 200,000 Filipino smokers are predicted to develop diseases related to smoking, and 20,000 deaths annually will be smoking-related.¹

There are a myriad of smoking cessation aids (SCA) comprised of methods and products that assist smokers in quitting through coping with psychological and physical aspects of nicotine dependence.² Nicotine replacement therapy (NRT), the most popular form of smoking cessation aid, acts by stimulating nicotinic receptors in the ventral tegmentum, eliciting the same effects of cigarette intake. NRT increases quit rates approximately 1 1/2 to 2-fold by reducing the symptoms associated with smoking cessation and by decreasing the urge to smoke.³

Another mode of SCA is acupuncture, a part of traditional Chinese medicine used in treating pain and other conditions stimulating anatomical points on the body with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.^(4,5) Part of the effectiveness of acupuncture is its analgesic effect. Studies showed a significant difference between smoking cessation in the acupuncture group and the group given no intervention.⁶ Acupuncture assists patients in overcoming the physical and emotional addiction to nicotine, and significantly reduces or completely eliminates the cravings and stress associated with the withdrawal process. Acupuncture focuses on jitters, cravings, irritability and restlessness; symptoms that people commonly complain about when they quit.

This study explored the efficacy of acupuncture compared with NRT in relieving withdrawal symptoms of smoking cessation. It sought to provide an alternative for the permanent relief of smoking. For a developing country with massive poverty, this is of utmost importance, especially for those who would want to quit smoking but have failed and could not afford the expensive NRT patches, gums or inhalers. The specific objectives of this study were: (a) To determine the effectiveness acupuncture in lessening the withdrawal symptoms related to cessation of smoking in adult smokers; (b) To determine the difference between the mean Wisconsin Smoking Withdrawal Scale (WSWS) scores of the acupuncture and NRT group; (c) To determine the mean scores of the subscales of the different aspects of withdrawal. The null hypothesis stated that there is no significant difference between the effectiveness of acupuncture and nicotine replacement therapy in reducing withdrawal symptoms.

METHODS

The study was a randomized controlled trial with subjects allocated to an acupuncture or nicotine replacement therapy group. Relief of withdrawal symptoms was measured with the Wisconsin Smoking Withdrawal Scale. This study was reviewed and approved by the Ethics Committee of UERMMMC. Figure 1 below shows a diagram of the study design.

Figure 1

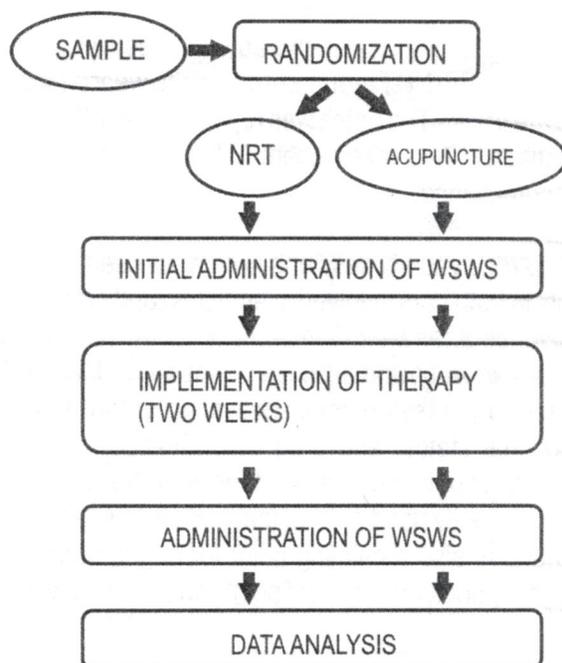


Figure 1. Flowchart of study procedure

Procedure

Recruitment of Subjects

Subjects were recruited by convenience sampling from among smokers referred to the researchers based on the following inclusion criteria: (1) male or female, 18 to 35 years old; (2) had unsuccessfully attempted to stop smoking at least once in the past month; (3) able to read and write sufficiently to understand and complete the forms; (4) willing to participate in a treatment protocol involving acupuncture and nicotine patches; (5) willing to abstain from smoking for at least two weeks; (6) able to abstain from smoking for at least 3-5 days prior to administration of treatment; and (7) had experienced withdrawal symptoms in the past when attempt to quit smoking was made. Subjects were excluded when they: (1) had any neurological or physical impairment that would prevent understanding of the research process; (2) were currently taking any of the following drugs: phenothiazines, tricyclic antidepressants, lithium carbonate, or beta-blockers, ephedra, ephedrine, amphetamines, or sedative medication. Participants were asked to sign a consent form and informed of the possible side effects of the treatments.

Wisconsin Smoking Withdrawal Scale

The Wisconsin Smoking Withdrawal Scale (WSWS) is a validated assessment of nicotine withdrawal, comprised of 28 items which focus on the major symptoms of withdrawal: irritability, depression, appetite, concentration, insomnia, anxiety, and the urge to smoke. It is self-administered and uses a 5-point scoring system (1 = strongly disagree, 5 = strongly agree). The WSWS has been used in determining withdrawal symptoms of smokers undergoing both psychological and pharmacological intervention to aid in cessation. The scale has a coefficient alpha of 0.90, suggesting strong internal consistency and reliability. It also has good predictive validity, with significant univariate differences for each subscale, when retested one day and weeks after the initial cigarette cessation. It is therefore sensitive to smoking withdrawal and is predictive of smoking cessation outcomes.^{7,8,9} Participants, under the supervision of two researchers, were made to answer the WSWS before and after the intervention they were randomized to using SPSS random number generator. The post-treatment WSWS was administered on the last day of the nicotine patch or after the last acupuncture session.

Intervention

Acupuncture and nicotine replacement therapy, respectively, were administered to each of the experimental groups for two weeks. The NRT group were made to wear a nicotine patch on the upper outer arm or on any clean, non-hairy part of the trunk. The patch was replaced every 24 hours; the new patch was attached to a different location to avoid irritation. Two researchers follow up the participants through standard daily text message reminders to ensure compliance.

The acupuncture group received six sessions from a licensed acupuncturist, with a maximum of three sessions per week. Five points in both ears involved in addiction and smoking were manipulated with needles as recommended by the acupuncturist: *Shen Men*, *Sympathetic*, *Liver*, *Lung 2* and *Kidney*. Shen Men point is used in addiction treatments, for stress, anxiety, and excessive sensitivity. Master Point Zero, subserves homeostatic functions, and stimulation leads to parasympathetic activation of the abdominal viscera and lungs. Positive effects on muscle tone, emotional status, and drug detoxification have also been recognized by auricular therapists. Lung 2 acupoint is for cough, asthma and tension in the chest, which can be an effect of cigarette smoking. The kidney acupoint is mostly used for nausea, headaches, anxiety and insomnia. The liver acupoint addresses nausea, insomnia and is also a calming point for anger, irritability and anxiety.^{10,12} Sterile half inch acupuncture needles were used in puncturing the said points and were allowed to stay there for 20 minutes..

Statistical Analysis

Paired *t*-test was used to compare the effectiveness of both treatments in reducing withdrawal symptoms. The individual withdrawal symptoms scores were also analyzed with a before and after *t*-test.

RESULTS

Twenty-two subjects were recruited for the study. The two groups had similar baseline characteristics ($p = 0.494$, Levine's test for equality of variances) as shown in Table 1.

Table 1. Baseline characteristics of participants

	Acupuncture Group	NRT Group	p-value
Female/male, %	5/6	5/6	0.670
Mean age (years)	24.64	24.18	0.765
Cigarettes smoked/day in past year	9.55	12.09	0.327
Mean pack/years history	3.94	4.81	0.543
No. of previous attempts to quit	3.55	3.45	0.934
Other smokers in the household (%)	6/11	6/11	0.670

As shown in Table 2, there was no significant difference in the mean scores of the symptoms after treatment except for urge to smoke, with the NRT group showing less urge.

Table 2. Mean scores of different aspects of withdrawal

Withdrawal Symptoms	Acupuncture group		NRT group		p-value
	Mean	S.D.	Mean	S.D.	
Irritability	9.36	1.963	8.18	2.040	0.182
Anxiety	8.77	2.149	8.73	1.758	0.065
Appetite	17.55	3.984	16.27	3.409	0.430
Insomnia	13.27	4.077	13.73	2.901	0.766
Urge to Smoke	14.55	3.417	11.45	2.911	0.033
Depression	11.45	2.697	11.27	3.003	0.883
Concentration	8.09	1.578	7.91	1.044	0.753

A comparison of the overall WSWS scores using a paired *t*-test showed that there was no significant difference in the mean withdrawal scores before and after treatment with either acupuncture or NRT. Neither was there any difference between the acupuncture and the NRT group.

Table 3. Comparison of the Mean Withdrawal Scores.

	Computed <i>t</i>	<i>p</i> -value
Pre- vs. Post-acupuncture	0.221	0.414
Pre- vs. Post-NRT	0.018	0.493
Post-acupuncture vs. Post-NRT	0.007	0.497

As shown in Figure 2, there was a general trend in the acupuncture group that pre-intervention mean withdrawal scores were higher than post-intervention mean withdrawal scores but the difference was significant only for sadness ($p = 0.022$, paired *t*-test), anxiety ($p = 0.000$, paired *t*-test), and concentration ($p = 0.002$, paired *t*-test).

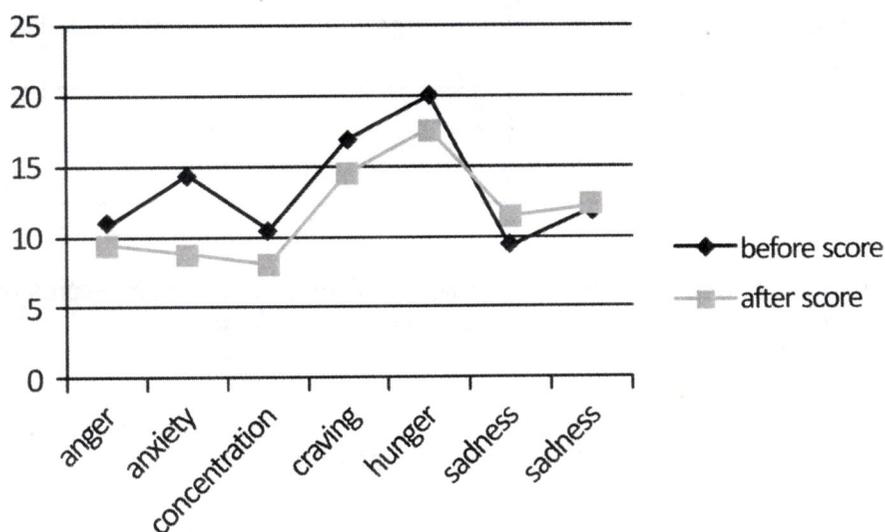


Figure 2. Trend of withdrawal scores in acupuncture group.

As shown in Figure 3, there was a general trend in the NRT group that pre-intervention mean withdrawal scores were higher than post-intervention mean withdrawal scores but the difference was significant only for sadness ($p = 0.013$, paired *t*-test), anxiety ($p = 0.000$, paired *t*-test), and sleep ($p = 0.048$, paired *t*-test).

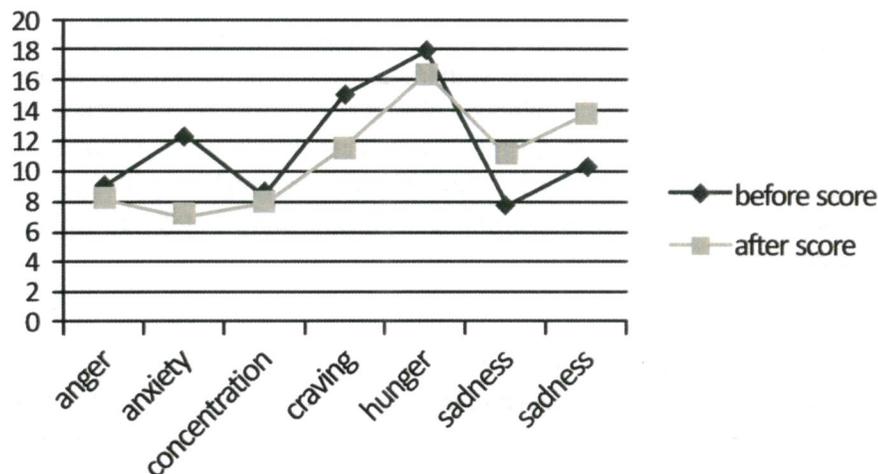


Figure 3. Trend of withdrawal scores in NRT group

DISCUSSION

Smoking and Withdrawal symptoms

Nicotine withdrawal is present if in the abrupt cessation of nicotine use or in the reduction in the amount of nicotine used, four (or more) of the following signs are exhibited within 24 hours: dysphoric or depressed mood, insomnia, irritability, frustration, or anger, anxiety, difficulty concentrating, restlessness, decreased heart rate and increased appetite or weight gain.¹⁰ Withdrawal symptoms can develop within 2 hours of smoking the last cigarette; they generally peak in the first 24 to 48 hours and can last for weeks or months.¹¹

Acupuncture and smoking cessation

Acupuncture is part of an array of traditional Chinese medicine (TCM) that have been present for more than a thousand years. TCM rests on the premise of having a balance between the elements of *ying* and *yang*. Forces move between these two elements in a balanced manner and this is called *Qi*.¹² Any imbalance, therefore, in the flow of *Qi* would result to illness, pain or susceptibility to illness. Therefore, TCM tries to re-create balance in the flow of *Qi* and inevitably, lessen illness or the risk of illness.

There have been several theories on the mechanism of action of acupuncture in relation to smoking cessation. One theory relates this effect to acupuncture's stimulation of endorphin release. Acupuncture stimulation can trigger the release of endorphins and enkephalins in the cerebrospinal fluid, thereby mimicking the role of nicotine in CNS stimulation. It was also hypothesized that acupuncture acts as a foreign body and in effect, stimulates vascular and immunomodulatory factors such as ACTH and endogenous corticosteroids, which are also released in nicotine stimulation.¹³

The effect of acupuncture on the brain can be explained through the Nerve-Reflex theory. This theory states that the autonomic nervous system extending through the internal organs, skin, subcutaneous tissues and muscles, constantly transmit information about the physical condition to the spinal cord and the brain. These information impulses set up a reflex action that causes symptoms of internal organ's disorders to manifest themselves on the surface area, known as the Viscera-Cutaneous Reflex. The same is true for the reverse. That stimulation of the skin and muscles can cause dilation or contraction of the vessels to change the blood and lymph flow of the internal organs, activate the endocrine and immune system. Therefore, when a needle punctures the skin, it sets off the latter discussed cutaneous-visceral reflex making the endorphin theory of acupuncture mechanism of action very plausible.¹³

Several studies have been done on the effect of acupuncture on smoking cessation. Hyun, Lee, Kang and Choi evaluated improvements in nicotine withdrawal symptoms, depression and anxiety in groups given acupuncture and sham acupuncture. Although the results show no significant difference between real acupuncture and sham acupuncture in decreasing nicotine withdrawal symptoms, there was a significant decrease in depression and anxiety.¹⁴ Kang HC, Shin KK, Kim KK, and Young BB found a significant decrease in desire to smoke among high school students who given acupuncture therapy on ear acupoints associated with aiding in smoking cessation.¹⁵

Nicotine Replacement Therapy

Nicotine replacement therapy is considered a standard SCA for smoking cessation. It reduces withdrawal symptoms by stimulating nicotinic receptors in the ventral tegmentum, thereby eliciting the same effects of cigarette intake.² Nicotine generally produces improved attention, learning and reaction times, and problem-solving abilities on short term exposure. It also causes elevation of mood, decrease of tension, increase in cerebral blood flow, and relaxation of skeletal muscles.¹¹ Nicotine patches release small doses of nicotine slowly and steadily which are absorbed into the bloodstream through the skin. It is usually administered in the morning and produces blood concentrations about half those of smoking.¹¹ Since the body has a constant supply of nicotine, the urge to smoke is reduced and withdrawal symptoms are minimized.^{2,16,17}

Statistical Analysis

Paired *t*-test showed no significant difference in the mean withdrawal scores before and after treatment with acupuncture. Previous studies have shown a significant difference in withdrawal scores between the acupuncture group and no intervention. However, the findings of this study was in agreement with findings from previous studies, wherein auricular acupuncture was administered for two weeks.¹⁶ Paired *t*-test also showed no significant difference in the mean withdrawal scores before and after NRT. This is in contrast with findings by Silagy et al (2004), where use of nicotine patches for eight weeks resulted in 1 1/2 to 2-fold increase in quit rates during a six-month follow-up. This discrepancy may be due to the short duration of transdermal patch administration.^{16,19} However, Kralikova et al. showed a decrease in withdrawal symptoms as early as two weeks. Finally, the paired *t*-test showed no significant difference in the post-treatment withdrawal scores between the acupuncture and NRT groups.

Paired *t*-test of individual withdrawal symptoms scores, however, showed a general decreasing trend after administration of both interventions. This finding may be due to the short duration of intervention. Traditional Chinese medicine suggests that treatment with acupuncture will immediately give results.^{4,12} However, the treatment duration may not have been sufficient to cause sufficient stimulation and adaptation of the body to the lack of nicotine in the blood.¹⁴ The lag between acupuncture sessions may have resulted in insufficient stimulation and subsequent production of hormones and other endogenous substances that would equal the effect of nicotine. On the other hand, the nicotine patches used had the lowest dose of nicotine per patch, which is usually used for maintenance and light-moderate smokers. The amount of cigarettes that individual participants were smoking was not taken into account and a single dosage of nicotine patches were used for standardization purposes. The small amount of nicotine per patch might not have been enough to cause stimulation in participants who were heavy smokers.

In conclusion, results of this study suggest that acupuncture therapy and NRT do not significantly lessen withdrawal symptoms. There was no significant difference between withdrawal symptoms of the acupuncture and NRT groups. However, there is a general decrease in individual withdrawal symptoms scores after the administration of both interventions. Moreover, acupuncture therapy significantly reduced anxiety and concentration.

For future studies, the duration of the treatment for both acupuncture therapy and NRT should be increased to allow for proper stimulation and adaptation to the lack of nicotine in the body. Furthermore, the individual cigarette consumption of the participants should be taken into account in giving the nicotine patches with the proper dosage. It is also possible to make use of other acupoints in the body that address individual withdrawal symptoms. Moreover, other forms of NRT, such as gums, may also be utilized to control the extraneous variable of nicotine amount in the patches. It is also advised to explore other forms of traditional Chinese medicine similar to acupuncture, such as acupressure, which may be administered by the researchers themselves as well as the participants, if given proper training.

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Article 3

A Retrospective Cohort Study of Ankle Inversion Sprain Injury and Leg Dominance among Runners

Rachel Ruth Koh, Milad Shafiei, Rayzielle Brenn Villasanta, Archelle Jane C. Callejo, PTRP, MSPH

College of Allied Rehabilitation Sciences

ABSTRACT

Introduction/Objectives: The overall objective of the study is to determine the relationship of ankle inversion sprain injury in the dominant and non-dominant leg among runners.

Methods: This was a retrospective cohort study to test the relationship of ankle inversion sprain injury and leg dominance among runners. Thirty-three runners with ankle inversion sprain in the dominant leg and 27 runners who had ankle inversion sprain in the non-dominant leg were recruited from various universities and runner's clubs/associations. Patients who had medical records or charts in a clinic within Metro Manila were also included. The relative risk was computed to determine the strength of association between ankle inversion sprain injury and the risk factors. Linear regression was used to determine the strongest indicator of ankle inversion sprain injury in the dominant and non-dominant leg, in relation to age, weight and height. An independent t-test was done to test the significance of means of two groups.

Results: Runners aged 15–32 years (low age; RR = 1.138), who weighed 61–90 kg (high weight; RR = 1.110) and had a height of less than 170 cm (low height; RR = 1.077) were more likely to sustain ankle inversion sprain. The strongest indicator of ankle inversion sprain in both the dominant and non-dominant leg was low age (15–32 years). A height less than 170 cm (low height) was a significant factor in the dominant leg.

Conclusion/Recommendations: There was a relationship between ankle inversion sprain injuries and low height (≤ 170 cm) in the dominant leg but not in the non-dominant leg. Low age (15-32 years) was the strongest indicator of ankle inversion sprain in both the dominant and non-dominant leg, however; it had a low association with a significance value of 0.184. There was an additional 25.9% increase in the risk of having ankle inversion sprain in the dominant and non-dominant leg if a runner had low age.

KEY WORDS: ankle inversion sprain injury, leg dominance, runner

INTRODUCTION

Ankle injury is one of the most common acute soft tissue injuries¹ and is considered as the second most common injury location, next to the knee.² Athletes, on the other hand, are predisposed to ankle injury since they engage mostly in activities like jumping and running which have been known to be the most common mechanism of injury. Among the injuries of the ankle, inversion injury most commonly occurs in athletes. The injury involves damage to the lateral ligaments, which consist of the anterior talofibular ligament, calcaneofibular ligament, and the posterior talofibular ligament; and ultimately results in pain, swelling, and limitation of movement.³

There are a growing number of people worldwide who engage in sports activities and exercises. Because of its convenience, running may be the most common exercise done by many people and the Philippines is no exception.

Nowadays, many Filipinos join marathons and "fun runs" for charitable causes. Besides its beneficial effects on health, running may cause injuries, especially to the lower extremities since the running gait involves 50 to 70 foot strikes per minute, each with a force of 3 to 8 times the runner's body weight, depending on the running terrain.⁶

During running, the foot is subjected to a high loading twice the body weight.⁴ In this gait, the ankle is in about 10° dorsiflexion during heel strike and rapidly dorsiflexes to 25° dorsiflexion. The rapid dorsiflexion is followed immediately by plantar flexion, which continues from the remainder of stance phase to the initial part of the swing phase. Plantar flexion reaches a maximum of 25° in the first few seconds of the swing phase. Throughout the rest of the swing phase the ankle dorsiflexes to reach about 10° in the late swing in preparation for heel strike.⁵ A running gait that involves 50 to 70 foot strikes per minute, each with a force of three to eight times the runner's body weight, depending on the running terrain, will cause running injuries, particularly in the lower extremities.⁶

Leg dominance, on the other hand, may be a risk factor for lower extremity injuries because most athletes place a greater demand on the dominant leg which results in increased frequency and magnitude of movements of the knee and ankle, especially during high-demand activities. Current literature is divided with regards to leg dominance as a risk factor for suffering an ankle sprain.⁸ The objective of this study was to determine if there is a significant relationship of age, gender, height and weight with ankle inversion sprain injury in the dominant leg and non-dominant leg among runners.

METHODS

The study protocol was approved by the UERMMMCI-College of Physical Therapy Ethics Review Board Committee. The information sheet and the written consent form, including purpose and procedures of this study were explained.

This retrospective cohort study was conducted using subjects from the Mega Clinic, University of the East Manila, University of Sto. Tomas, Ateneo de Manila University, De La Salle University, Adination Runner's Club, Bhoj Runner's Society, Run Manila Society, A Runner's Circle, Team Bald Running Club, Happy Feet Club and Running Bananas Club. A runner was eligible if he/she fulfilled the following criteria: (1) age 15-50 years; (2) ran a minimum of 20 km per week on a regular basis; (3) ran consistently for at least one year; and (4) had a history of ankle inversion sprain injury. A runner was excluded if: (1) injury to the ankle other than inversion sprain; (2) injury or any condition that would limit joint movement in any part of the body; (3) severe medical or orthopedic complications; (4) severe co-morbidities including degenerative diseases of the knee (osteoarthritis), rheumatoid arthritis, or any musculoskeletal or cardiovascular disorders.

Data was obtained through combination of review of medical records, telephone calls, and/or questionnaires that determined their age, gender, height, weight and affected leg with ankle inversion sprain injury. An assessor who was not part of the research team screened the participants for eligibility. Eligible participants were classified according to the age (45-50, 39-44, 33-38, 27-32, 21-26 and 15-20 years), weight (81-90, 71-80, 61-70, 51-60, 41-50 and \leq 40 kg), height (191-200, 181-190, 171-180, 161-170, 151-160 and \leq 150 cm), gender, and ankle inversion sprain acquired on the dominant or non-dominant leg based on their handedness. The data groups in the tally sheet were further divided as: high age (33-50 year), low age (15-32 years), high weight (61-90 kg), low weight (\leq 60 kg), high height (171-200 cm) and low height (\leq 170 cm).

All data were encoded in Microsoft Excel and SPSS Statistical Package ver. 17 for analysis. The rate of occurrence for each variable (age, weight, height, gender, and ankle inversion sprain on the dominant and non-dominant leg) item was obtained. Test for the strength of association between ankle inversion sprain injury in the dominant leg and non-dominant leg, in relation with high age, low age, high weight, low weight, high height and low height was obtained using risk ratio. Multivariate analysis through linear regression was used to determine the strongest predictor among the variables mentioned. An independent t-test was used to determine the relationship between ankle inversion sprain in the dominant and non-dominant leg and age, weight, height.

RESULTS

A total of 60 runners were included in the study, 33 of whom had ankle inversion sprain in the dominant leg and 27 in the non-dominant leg. A flow of subject participation is illustrated in Figure 1.

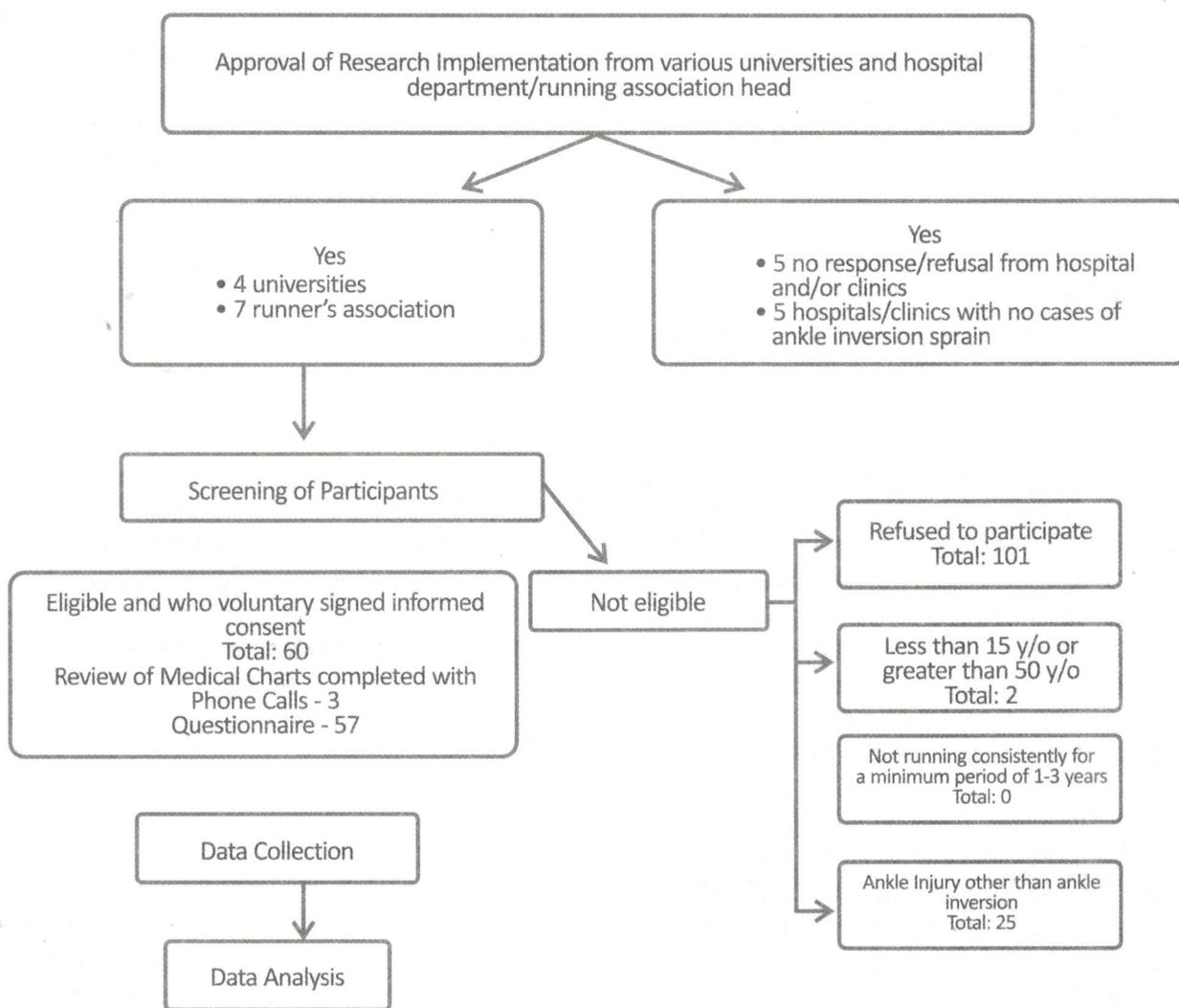


Figure 1: Research flow of the study participants

As shown in Table 1, the age group 15-20 years had the highest number (45.45%) of ankle inversion sprain in the dominant leg while the age group 21-26 years had the highest number (48.15%) among runners with ankle inversion sprain in the non-dominant leg. The weight bracket 61-70 kg had the highest incidence (27.27%) in the dominant leg while the 51-60 kg and 61-70 kg groups had the highest occurrence (33.33%) in the non-dominant leg. The occurrence of ankle inversion sprain was highest in the height bracket 161-170 cm (69.70% for the dominant leg and 37.04% for the non-dominant leg). Majority of runners who had ankle inversion sprain were males, 75.75% in the dominant leg and 70.37% in the non-dominant leg.

Table 1: Demographic Characteristics of Runners

Variables	Dominant Leg n=33		Non - Dominant Leg n=27	
AGE				
• 45 – 50 y/o	0	0%	0	0%
• 39 – 44 y/o	0	0%	1	3.70%
• 33 – 38 y/o	1	3.03%	3	11.11%
• 27 – 32 y/o	5	15.15%	3	11.11%
• 21 – 26 y/o	12	36.36%	13	48.15%
• 15 – 20 y/o	15	45.45%	7	25.92%
WEIGHT (kg)				
• 81 - 90	2	6.06%	1	3.70%
• 71 - 80	8	24.24%	4	14.81%
• 61 - 70	9	27.27%	9	33.33%
• 51 - 60	7	21.21%	9	33.33%
• 41 - 50	7	21.21%	4	14.81%
• 0 - 40	0	0%	0	0%
HEIGHT (cm)				
• 191 - 200	0	0%	0	0%
• 181 - 190	1	3.03%	0	0%
• 171 - 180	7	21.21%	8	29.62%
• 161 - 170	23	69.70%	10	37.04%
• 151 - 160	1	3.03%	8	29.62%
• 0 - 150	1	3.03%	1	3.7%
GENDER				
• Male	25	75.75%	19	70.37%
• Female	8	24.24%	8	29.63%
HISTORY				
• Completed with phone calls	3	9.09%	0	0%
• Completed without phone calls	30	90.90%	27	100%

Rate of occurrence/percentage of runners with ankle inversion sprain in the dominant and non-dominant leg according to age, height, weight, gender

The variables associated with ankle inversion sprain were low age (RR = 1.138), high weight (RR = 1.110), and low height (RR = 1.077) as shown in Table 2. Runners aged of 15–32 years were 1.138 times more likely to have ankle inversion sprain than runners aged 38–50 years (high age). Runners weighing 61–90 kg (high weight) were 1.110 times more likely to have ankle inversion sprain than those runners with a weight of ≤ 60 kg (low weight). Also, runners with low height (≤ 170 cm) were 1.077 times more predisposed to ankle inversion sprain than runners with a high height.

Table 2: Relative Risk for the Strength of Association between ankle inversion sprain in the dominant and non-dominant leg and risk factors (age, weight and height)

VARIABLES	RELATIVE RISK
HIGH AGE (33-50 y/o)	0.205
LOW AGE (15-32 y/o)HIG	1.138
H WEIGHT (61-90 kg)	1.110
LOW WEIGHT (0-60 kg)	0.881
HIGH HEIGHT (171 – 200 cm)	0.818
LOW HEIGHT (0 – 170 cm)	1.077

Relative Risk value for each variable (age, weight and height) in relation to the dominant and non-dominant leg.

Linear regression showed that the strongest indicator of ankle inversion sprain injury in both the dominant and non-dominant leg was low age. However; it had a low association with $p = 0.145$. Low age also produced a 25.9% increase in the risk of ankle inversion sprain in the dominant and non-dominant leg. The mean age, weight and height of the dominant and non-dominant leg groups were compared in Table 3. Levine's test for equality of variance and independent t test showed a significant association between low height and ankle inversion injury ($p = 0.003$, t-test, unequal variance) as shown in Table 4. Age and weight were not significant predictors of injury.

Table 3: Comparison of mean age, weight and height for ankle inversion injury in dominant and non-dominant leg groups

	Ankle Inversion	N	Mean	Std. Deviation
High age	Dominant	1	37.0000	.
	Non-dominant	4	36.5000	2.38048
Low age	Dominant	32	21.2500	3.48268
	Non-dominant	23	22.7391	3.92217
High weight	Dominant	19	69.7368	9.91543
	Non-dominant	14	68.9286	5.25451
Low weight	Dominant	14	51.5714	5.30188
	Non-dominant	13	52.0769	3.88290
High height	Dominant	8	178.0000	4.65986
	Non-dominant	8	176.7500	1.75255
Low height	Dominant	25	165.2000	4.14327
	Non-dominant	19	161.2105	6.83601

Table 4: Statistical analysis for difference in means for age, weight, height for ankle inversion injury runners between dominant vs non-dominant leg group.

		Levine's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	p value
High age	Equal variances assumed			.188	3	.863
	Equal variances not assumed					
Low age	Equal variances assumed	0.205	0.653	-1.484	53	0.144
	Equal variances not assumed			-1.455	43.977	0.153
High weight	Equal variances assumed	4.365	0.045	.277	31	0.784
	Equal variances not assumed			.302	28.586	0.765
Low weight	Equal variances assumed	4.844	0.037	-.281	25	0.781
	Equal variances not assumed			-.284	23.765	0.779
High height	Equal variances assumed	2.155	0.164	.710	14	0.489
	Equal variances not assumed			.710	8.941	0.496
Low height	Equal variances assumed	9.589	0.003	2.400	42	0.021
	Equal variances not assumed			2.249	27.827	0.033*

* - statistically significant at $p=0.05$

DISCUSSION

Ankle inversion sprain is a common injury in runners. The injury involves damage to the lateral ligaments, and results in pain, swelling, and limitation of movement.³ Ankle inversion sprain injury usually occurs during loading and unloading phase but not when ankle is fully loaded. It is also influenced when foot is plantar-flexed and forefoot is made to contact the ground first.⁴ On initial contact of the foot the ankle is in closed kinetic chain (DF) wherein the joint is stabilized. Pronation of the foot is influenced by the ground reaction forces against the calcaneus as the lower extremity receives weight (subtalar joint eversion and abduction, ankle mortise PF, talar adduction, and IR of tibia). Foot ground pressure distribution on each foot varies during different phases of gait. It can be used to evaluate corresponding pressure intensity on foot anatomy. Pressure values and distribution can be used to determine resultant forces applied to different foot regions that may be useful for further analysis.⁸ During the initial contact of foot in the stance phase of gait, when the plantar pressure is laterally situated there would be more risk in sustaining ankle inversion sprain.¹⁰

Common risk factors included in this study were age, height, weight, and leg dominance. Recent evidence showed that the dominant leg may be at increased risk of injury because it is always used for kicking, pushing off, jumping, or landing. Several risk factors studies have reported that leg dominance has an effect on lower extremity injury.⁹ Leg dominance has been identified as a risk factor for lower extremity injuries because most athletes place a greater demand on the dominant leg which results in increased frequency and magnitude of moments on the knee and ankle, especially during high-demand activities.⁸

This study found that there was a higher incidence of ankle inversion sprain in the dominant leg (n=33) than the non-dominant leg (n=27) in both males and females. There was also an increase in the frequency of runners with ankle inversion sprain in the age group 15-20 years, weight group 61-70 kg, and height group 161-170 cm in the dominant leg. In the non-dominant leg, the frequency was higher in the age group 21-26 years, weight groups 51-60 kg and 61-70 kg, and height group 161-170 cm. Runners with low age, high weight and low height were more likely to sustain ankle inversion sprain. Based on linear regression, the strongest indicator of ankle inversion sprain in both the dominant and non-dominant leg was low age; however, independent t-test showed low height was more significantly associated with ankle inversion sprain in the dominant leg; there was no significant association in the non-dominant leg.

The determination of the relationship of ankle inversion sprain injury in the dominant leg to height would help physical therapists, sport trainers, and the runners to increase awareness in implementing injury prevention protocols in the dominant leg when the runner's height is ≤ 170 cm. This would also hold true for runners in the 15-32 year old bracket.

A limitation of this was a lack of homogeneity in age, gender, weight and height variables of runners, although the participants came from the same population. Other limitations were low sample size and lack of studies that would support the results of this study. The determination of the association between the development of ankle inversion sprain injury in the dominant leg, in relation to height and age, will pave way for further studies. The results of this study could be utilized to develop future scoring systems in assessing individuals engaged in running and implementing injury prevention protocols.

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Article 4

An Experimental Study on the Effectiveness of Educational Intervention on the Compliance of Healthcare Workers in a Tertiary Hospital to the 2010 WHO Hand Hygiene Guidelines

Augusto Niccolo S. Salalima, M.D.

Department of Internal Medicine

ABSTRACT

Introduction/Objectives: Healthcare associated infections have a direct relationship with compliance to hand hygiene. Despite previous development of hand hygiene guidelines, compliance to proper hand hygiene among healthcare workers remains poor. This led to the development of the 2010 WHO Hand Hygiene Guidelines. The aim of this study was to determine the impact of low budget educational interventions on compliance with hand hygiene in a setting with limited resources and to determine the compliance rate to the 2010 WHO Hand Hygiene Guidelines.

Methods: This was an experimental study conducted in 3 randomly selected wards in a tertiary hospital from July to September 2011. Hand hygiene compliance among healthcare workers in the selected wards was determined by direct-observation before and after an educational intervention. Percentages and chi square test were computed.

Results: Overall baseline compliance to the 2010 WHO Hand Hygiene guideline was 26.51%. After educational interventions, the overall compliance increased to 32.14% ($p = 0.0001$). The compliance to proper hand hygiene increased in the 3 wards and among all healthcare workers after the educational intervention. Clinical clerks, nurses, and residents were the most compliant. The healthcare workers were compliant to proper hand hygiene mostly before a clean/aseptic procedure but least after touching the patient's environment.

Conclusion: Low budget educational interventions can have a scientific and practical impact to make a difference to the compliance among healthcare workers to proper hand hygiene in different wards of a tertiary hospital.

KEY WORDS: Hand hygiene, guidelines, compliance, WHO

INTRODUCTION

Healthcare-associated infections have been a major concern regarding patient care in hospitals in both developed and developing countries. Thus, its surveillance and prevention must be a first priority for institutions committed to making health care safer.¹

Healthcare workers' hands are the most common vehicle for the transmission of healthcare-associated pathogens from patient to patient and within the healthcare environment.³ Studies have shown that hands of health care workers can be contaminated by bacterial or viral pathogens. For example, Bhalla et al. demonstrated that patients with skin colonized with MRSA can be transferred to the health care workers' hands and infect another patient.⁴ It has also been demonstrated that during patient care, the hands of healthcare workers are progressively colonized with different microorganisms, and in the absence of hand hygiene, the longer the duration of care, the higher the risk of hand contamination.^{1,3} This resulted to an increased rate of healthcare-associated infections in different healthcare settings in both developed and developing countries.

Several studies done abroad have proven the causal relationship between non-compliance to hand hygiene and healthcare-associated infections.²⁻¹⁰ Locally, there is only one study in 2001 which described the hand washing practices of health workers in an ICU setting in a tertiary hospital.²

From the simple soap and water to the many alcohol-based disinfectants now present, hand hygiene has been a part of patient care. There have also been many studies done proving its role in preventing or decreasing the risk for nosocomial infections particularly in ICU settings.^{1,2,5-7} Despite the different guidelines on hand hygiene and the different measures adopted by many hospitals, the compliance of healthcare workers to hand hygiene have continued to be poor⁸. Hence, the WHO developed the 2010 Guidelines on Hand Hygiene in Health Care to promote adherence among healthcare workers to hand hygiene in order to decrease the risk of patients in acquiring healthcare-associated infections.

Several studies have already established different factors or barriers on the compliance with hand hygiene among healthcare workers such as being a physician, male sex, high patient-to-nurse ratio, insufficient time, lack of institutional guidelines, and lack of knowledge, education, and experience to proper hand hygiene techniques.⁹⁻¹¹ However, there are limited studies that assessed the role of education in the compliance of healthcare workers with hand hygiene, especially in developing countries, such as the Philippines. Panaligan *et al*, showed that with lectures and posters on hand hygiene techniques, compliance of healthcare workers in the ICU improved but still did not achieve the target.¹²

The aim of this study, therefore, was to compare compliance of healthcare workers in different hospital wards/units of a tertiary hospital to the 2010 WHO Guidelines on Hand Hygiene before and after an educational intervention and to describe the most common methods used for hand hygiene among healthcare workers in the different hospital wards both before and after an educational intervention.

METHODS

This was an experimental study conducted at three randomly chosen wards picked by an independent observer through cluster sampling in a tertiary hospital from July to September 2011. The Medicine-ICU (intensive care units), 4 South (pay), and Neurology Ward (charity) had capacities of 3, 25 and 15 beds, respectively. The target population were the consultants, residents, postgraduate interns, clinical clerks, nurses, nurse aides, respiratory therapists, and medical technologists rotating or assigned in the respective wards during the study period.

The terms listed were used and defined as follows:

- *Opportunities* - situations in which hand hygiene was required or appropriate as stated in the WHO guidelines. This is also known as the "Five moments of Hand hygiene": (1) before touching the patient; (2) before a clean/aseptic procedure; (3) after body fluid exposure; (4) after touching the patient; and (5) after touching the patient's environment.
- *Compliance* - occasions in which the healthcare workers adhered to the recommended hand hygiene techniques as stated in the WHO guidelines.
- *Noncompliance* - occasions when the healthcare worker did not practice hand hygiene or did hand hygiene but with the wrong technique as stated in the WHO guidelines.
- *Hand hygiene* - the use of soap and water, alcohol-based disinfectants, or gloves, or any method or preparation included in the WHO guidelines, by healthcare workers during patient care.

According to the 2010 WHO Guidelines on Hand Hygiene in Health care, the number of samples needed in order to assess improvement in compliance in hand hygiene and have a stable distribution of data points for analysis is at least 15-20 opportunities/day for a span of 10 days each per ward¹.

On the first month of the study, the investigator conducted direct observation of healthcare workers to the proper hand hygiene techniques 8 hours daily for 10 days to determine baseline compliance. The time of the day and days of the week that the wards were observed were randomized. All data were recorded using a data collection tool and the results were presented in percentages.

During the second month, the investigator conducted frequent low-budget educational interventions through lectures, posters, and verbal reminders among healthcare workers in the three wards. Two 30-minute PowerPoint lectures were held on two Saturdays and covered (1) the association of hand hygiene compliance and healthcare-associated infections; (2) 2010 World Health Organization Guideline on Hand Hygiene; (3) the "Five Moments of Hand Hygiene", and; (4) proper hand hygiene technique and appropriate hand washing preparations/methods. Hospital-provided posters on the proper hand washing technique were made available and visible beside the washing area of the three chosen wards. Three (3) sessions per week was allotted to explain the posters to the healthcare workers and demonstrate the proper hand washing technique. Throughout this period, constant verbal reminders to the healthcare workers on the "Five Moments of Hand Hygiene" and compliance to the proper hand hygiene technique were done. No determination of compliance was done during this period.

On the 3rd month, a post-intervention compliance determination was performed as previously described and recorded. The results of compliance between the pre- and post-intervention periods were compared and analyzed using chi-square test.

RESULTS

There were 5605 hand-washing opportunities before the educational intervention and 4947 hand washing opportunities after. The highest frequency was observed among the clinical clerks (25.84%), followed by the nurses (19.08%), and residents (18.36%). This was consistently seen in the three wards and during both the pre- and post-intervention periods. They also had highest compliance rates in both the pre- and post-intervention periods. As shown in Table 1, there was an absolute increase in the compliance across all health care workers. There was a statistically significant difference in compliance among all the health care workers before and after the educational intervention except among the postgraduate interns, nurse aides, respiratory therapists, and medical technologists.

Table 1. Cumulative compliance rate among healthcare workers to the proper hand hygiene

	Pre-Intervention	Post-Intervention	Chi square	2-tailed p value
Consultants	63/275 (22.91%)	110/333 (33.03%)	7.094	0.0077
Residents	289/1078 (26.81%)	290/859 (33.76%)	10.694	0.0011
Postgraduate Interns	165/598 (27.59%)	174/590 (29.49%)	0.436	0.5088
Clinical Clerks	449/1586 (28.31%)	396/1141 (34.71%)	12.398	0.0004
Nurses	280/1044 (26.82%)	329/970 (33.92%)	11.674	0.0006
Nurse Aides	130/513 (25.34%)	167/552 (30.25%)	2.951	0.0858
Respiratory Therapists	84/389 (21.59%)	96/374 (25.67%)	1.537	0.2150
Medical Technologists	26/122 (21.31%)	28/128 (21.88%)	0.012	0.9138

The Neurology Ward showed the highest compliance among the three wards during both the pre- and post-intervention periods (Table 2). All the three wards showed an increase in compliance after the educational intervention, but the most significant improvement was seen in 4South. The baseline compliance was 26.51% and increased to 32.14% after the educational intervention ($p = 0.0001$).

Table 2. Compliance Rate per Ward

Ward	Pre-Intervention	Post-Intervention	2-tailed p value
Medicine-ICU	28.63%	31.91%	0.0377
4 South	23.13%	31.79%	0.0001
Neurology Ward	29.58%	33.11%	0.0645
Overall	26.51%	32.14%	0.0001

Among the "5 Moments of Hand Hygiene", compliance was 100% before a clean/aseptic procedure but poor after touching the patient and after touching the patient's environment (Table 3). There was an absolute improvement noted after the educational intervention in each of the "5 Moments of Hand Hygiene" and was statistically significant except for compliance after exposure to body fluid.

Table 3. Cumulative compliance rate to hand hygiene among healthcare workers in relation to the "5 Moments for Hand Hygiene"

Moment	Pre-Intervention	Post-Intervention	2-tailed p value ($p < 0.05$)
Before touching the patient	417/1570 (26.56%)	445/1385 (32.13%)	0.0010
Before a clean/aseptic procedure	280/280 (100%)	248/248 (100%)	---
After exposure to body fluid	269/957 (28.11%)	270/842 (32.10%)	0.0756
After touching the patient	343/1570 (21.85%)	350/1385 (25.27%)	0.0317
After touching the patient's environment	177/1228 (14.41%)	277/1087 (25.48%)	0.0001

The most common preparation for hand hygiene was soap and water. This was consistently observed among the three wards and during both the pre- and post-educational intervention periods. There was an increase in the use of (Sterillium) after the education intervention but was not statistically significant ($p = 0.1065$).

DISCUSSION

There have been many studies that determined the compliance rate of healthcare workers to previous hand hygiene guidelines.¹³ This study is different from the previous ones in 3 main points: (1) it determined the compliance of healthcare workers to the 2010 WHO Hand Hygiene Guideline, specifically the compliance rate to each of the "5 Moments of Hand Hygiene"; (2) this study was not limited to intensive care units but included the other wards in a tertiary hospital; and (3) this was an experimental study where a series of educational interventions was done to determine if it improved compliance. The three wards involved in this study (Medicine-ICU, 4 South, and Neurology Ward) represented the general ward composition of the hospital: intensive care units (Medicine-ICU), pay wards (4 South), and service wards (Neurology ward). This study was conducted to determine the effect of low budget educational interventions to the compliance of healthcare workers to hand hygiene.

Compliance across the three wards significantly improved after only one month of educational interventions. However, the overall compliance both before and after the educational intervention in this study was lower than the compliance noted in other studies which ranged from 48-64%.^{1,3,13} In fact, the 32.25% compliance to hand hygiene after the educational intervention was still low when compared to previous studies and guidelines.¹²⁻¹³

Among the healthcare workers, the clinical clerks, nurses, and residents had the most hand washing opportunities. Consequently, this study also showed that these three groups of healthcare workers had the highest compliance both before and after the educational intervention. This is important as the clinical clerks, nurses, and residents are the "frontliners" in patient care in this tertiary hospital. They had the most encounters with patients and could possibly increase transmission of healthcare-associated infections from patient to patient. If the group of healthcare workers with the most frequent patient encounters were also the most compliant to proper hand hygiene, then the rate of healthcare-associated infections in a particular hospital may be limited. It is also important to emphasize that the improvement in compliance was seen among all the groups of healthcare workers included in this study. The study also confirmed the findings of previous studies showing that nurses were more compliant than physicians (consultants and residents) to hand hygiene.

In relation to the "Five Moments of Hand Hygiene" as stated in the WHO guideline, there was 100% compliance to proper hand hygiene before a clean/aseptic procedure as this was already common practice in this tertiary hospital even before this study was conducted. The more important things to note were the moments in which healthcare workers tended to oversee: before touching the patient, after touching the patient, and after touching the patient's environment. The previous studies cited compared compliance before and after touching the patient. In this study, compliance increased before touching the patient, after touching the patient, and after touching the patient's environment. The healthcare workers became more aware that hand hygiene was required in these moments of patient care.

In summary, this study was able to show that even low budget educational interventions could improve the compliance to a hand hygiene guideline in different wards and among healthcare workers in a tertiary hospital. However, the improvement noted in this study is still not enough and is still low compared with compliance noted in previous studies. Thus, the author recommends that other studies be done regarding the following issues with regards to hand hygiene compliance:

1. The education intervention be institutionalized so that the information to be disseminated is uniform and more organized, and a larger population can be reached;
2. The educational intervention period be extended to a 6-month or 12-month period with monthly performance feedback to the different wards and healthcare workers which can be used by the tertiary hospital as part of the evaluation/assessment of their healthcare workers;
3. The association of compliance to hand hygiene and rate of healthcare-associated infections be determined;
4. Hand hygiene compliance in the operating room, delivery rooms, neonatal intensive care units, out-patient department, and emergency room be determined; and
5. The hand hygiene compliance of patient's companions and its effects be determined.

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Article 5

Multi-Level Approach: Evaluating Learning Outcomes

Wilhelmina Z. Atos, RN, PhD; Belinda M. Capistrano, RN, MAN; Jocelyn M. Molo, RN, MPH; Maria Luisa T. Uayan, RN, MSN

College of Nursing

ABSTRACT

Introduction/Objectives: The study was done to determine whether or not a Multi-Level Approach (MLA) could cause some changes in the skill competency that three levels of learners are expected to practice at defined levels of proficiency in health care. Specifically, it sought to determine relationships and differences among the 10 dimensions of caring activities after MLA exposure within and among learners across settings.

Methods: In this non-experimental design study, 24 samples were selected based on the Related Learning Experience (RLE) rotation schedule, stratified according to academic performance, and randomly assigned to the clinical setting. Two faculty facilitators handled the two groups for two weeks at 40 hours per week. Competency assessment along the 10 dimensions of caring activities were done before and after exposure to MLA using a performance evaluation tool adapted from the Board of Nursing competencies content validated by a panel of experts. Multivariate analysis using SPSS version 14 generated results of relationships and differences among variables identified to test the hypotheses at 0.05 level of significance.

Results: Moderate significant relationships in *advances ethico-legal activities* ($r = 0.523, p = 0.009$), *accountability* ($r = 0.523, p = 0.009$), *nursing process/therapeutics* ($r = 0.513, p = 0.010$), and *competence in communication* ($r = 0.414, p = 0.044$) were found only after exposure to MLA; significant differences were noted in all dimensions ($t = -2.584$ to $-5.100, p = 0.000$ to 0.017). ANOVA test of significant differences within and between groups across settings was significant for *competence in communication* ($F = 19.479, p = 0.003$), *critical thinking* ($F = 14.167, p = 0.005$), *application with theory* ($F = 11.25, p = 0.009$), *scientific support* ($F = 7.5, p = 0.021$) and *advances ethico-legal activities* ($F = 5.00, p = 0.04$). Safe performance was enhanced after MLA exposure.

Conclusion: The Multi-Level Approach strategy in clinical supervision enhanced the attainment of a safe, competent and efficient level of performance. Performance level was higher after MLA exposure. There was a significant difference in the clinical learning outcomes between and among groups of learners. The Social Interaction Theory of Vygotsky was affirmed.

KEY WORDS: Multi-level approach, nursing education

INTRODUCTION

The challenges confronting nurses in today's rapidly changing health care environments have highlighted the necessity for graduating students to feel both competent and prepared for practice. Nursing educators realize that clinical practice is a significant and essential part of a student nurses' education as the quality of nurse education depends largely on the quality of the clinical experience.^{1,2} This has in turn highlighted the increasing significance of the nature and quality of student clinical learning experiences.³⁻⁷ Nursing graduates are required to have adequate knowledge and skills, and are expected to be able to transform competencies into effective performance.⁷ Clinical practice stimulates students to use their critical thinking skills for problem solving.⁸ Problems that affect the students' clinical learning such as stress, anxiety, the initial clinical experience and the theory-practice gap⁹ may lead to their failure to learn and rejection of the nursing profession.¹⁰ Clinical learning outcomes however are accomplished in opulent, realistic environments far removed from the ideal.¹¹

The clinical setting offers opportunities for student nurses to work with real clients with real problems. It is only in the clinical setting that they can use knowledge in practice, develop competency in psycho-motor skills and become socialized in their future role.¹² Effective clinical placements allow the application of theory to practice.² These experiences are central to the student's preparation for entering the workforce as a competent and independent practitioner.¹³ It is during their clinical placement that students are expected to develop the relevant knowledge, skills and competence,⁴ to develop their capacity for "knowing how" as well as for "knowing that"^{5,6} and to expand their perceptions of their future role as a registered nurse.

The Related Learning Experience (RLE) is supposed to complement the classroom structure as the emphasis can be on the affective dimension. Answers to "how" and "when" of nursing care become the motivating source of affective and psychomotor learning. RLE thus complements the cognitive dimension of an individual learner. This opportunity for affective development is, however, seemingly neglected area as the clinical supervisor tends to be more "cognitive" with more on the "quiz" or summative evaluation mode rather than on the "helping" or formative mode. It is in this area that the multi-level approach clinical instructional design hopes to bridge the gap on holistic development of learners.

There is a dearth of literature on the multi-level approach as applied to the related learning experience tool of supervision. The major approaches related to group work, group process are mostly in the classroom setting.¹⁴⁻¹⁶ These classroom approaches, often called collaborative learning, are said to enhance student thinking. Another limitation of the present literature is that the dependent measures and outcomes as competency (skills) along the ten (10) dimensions of caring activities have not been studied for groups of learners in different levels. Some practices in group learning vary according to grouping procedure, development of group work skills, interdependence structure set up and evaluation procedure.¹⁵ What is lacking or perhaps overlooked is a consideration of the rationale for students working together in groups either in the classroom or clinical instruction environment.

Increasingly there is a need for evidence to guide related learning practice, including the use of group learning in three levels of student learners. A pilot study by Ramos, Capistrano et al in 2009 explored the initial impact on student-staff relationships and self-reported student competency by focused group. It is important to explore further how the multi-level approach promotes the proximal development of student learning outcomes within and between groups and explore how students in one level who interact with other levels promotes quality nursing care. To fill the gaps, the research core faculty of UERM College of Nursing examined the clinical learning outcomes of the three (3) levels of learners when the approach coined as Multi-level Approach (MLA) was utilized.

The strong point of this model is the emphasis on the *affective dimension* of development using group process. Eugene Moran, SJ¹⁶ said that the affective dimension is concerned on the "how" and the "when" needed by the learner for him to commit to a more effective course of action - the performance of nursing care through shared goals. Will there be a difference in what a student learner can perform alone and what she/he can accomplish with guidance from a more advanced peer in the clinical setting when a multi-level approach is utilized?

The primary purpose of this study was to determine whether the MLA caused a change in the skill competency that the three (3) levels of learners were expected to practice at defined levels of proficiency in health care. Specifically, it addressed the following research questions:

1. What is the performance level of the group of learners before and after utilization of Multi-Level Approach? What is the most/least competent dimension?
2. What significant relationships exist among the 10 dimensions of caring activities and the learners clinical learning outcomes?
3. What changes occur in performance level from 2 weeks (40 hours) to 4 weeks utilization of MLA for student group of learners across settings from actual to desired learning outcomes?

It is hypothesized that MLA enhances the acquisition of performance competency standard; that a relationship exists between the learning needs before and learning outcome after exposure to MLA; that there is a significant difference in the learning outcome between and among groups of learners.

The conceptual framework is shown in **Figure 1** below.

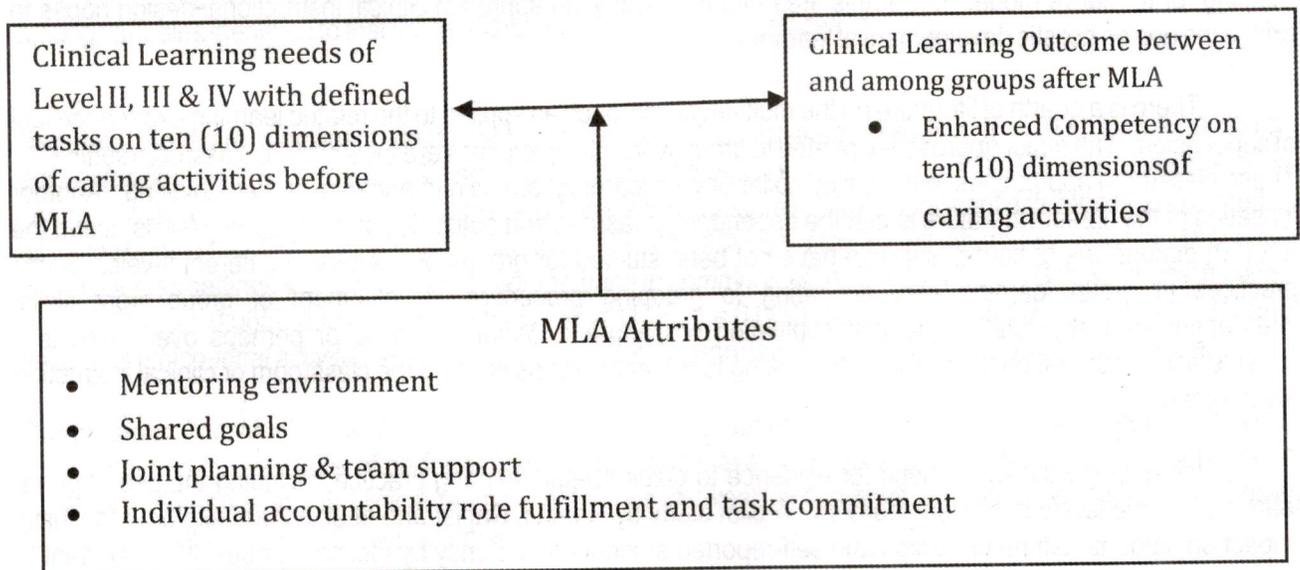


Figure 1. Schematic diagram of relationship of student clinical learning need and learning outcomes before and after exposure to Multilevel Approach.

The Multi-Level Approach (MLA): Laying the groundwork for facilitating learning outcomes in the Clinical setting

The model described here is an instructional paradigm and a simplified version of collaborative/participative learning. It operated on the premise that a competent and expert faculty can function as a generalist in the clinical educational environment and can handle three (3) levels of student learners. The MLA is a TEAM CONCEPT with three levels of students under the mentorship of a faculty. It is more than multi-functional. The group clinical learning task is designed based on shared learning goals. As stated by our Dean Carmelita Divinagracia, "the three levels complement each other to produce an outcome of quality nursing for clients." The model attempts to sketch the interaction between *relationship* dimension and *work/task* dimension in an RLE group of three levels of learners. As a learning team, the central focus is the individual with a clinical learning need, with defined individual accountability, role fulfillment and task commitment. The individual with specific clinical learning needs is part of a Team-group of learners.

The Multi-Level Approach has the following attributes: (1) shared clinical learning goals, (2) team support, (3) joint planning, (4) individual accountability, task commitment and role fulfillment, (5) Scaffolding clinical instruction, and (6) clinical environment where (under a mentor) group skills, 3 level-grouping and evaluating procedures, promote a sharing of learners' alternative viewpoints in support of each other's quest for quality care. Acquisition of the whole range of skill competency that the different level of learners is expected to practice may be affected by the level of relationship within and between groups and work issue or task/goals to be achieved.²⁰ As this model is a group process approach, it gives the context of social responsibility of the mentor to be relevant to the needs of his learners. The environment where the three levels of group learners are exposed is the social interaction milieu where mutual trust and mutual support are motivated. It is characterized by genuine communication, respect for individual differences, and conflict seen as a normal occurrence.

The group interdependence is encouraged using K – W – H – L – S¹⁷ (Reid, 1989) modified to KWHLSO strategy to ensure that every student pursues goals that are individually beneficial and yet congruent with the RLE group's common goal in the clinical learning activity. The faculty mentor initially explores with how much input should be given for learning tasks, and how much is left to the resourcefulness of the students. An example of the modified process used by MLA: K = "What I Know" (actual level of clinical assessment skills); W = "What I Want to learn" (Assessment skill on a particular concept); H = "How I will learn and work with others to attain mutual goals" (bring in information about assessment skill of a particular concept, share the idea to the group and compare perspectives); L = "What I Learned" (Evaluating what I found and How I can use it individually and group); S = "How I share and will share what I learned from others" (Writing a joint report/documentation for nurses notes in team's case load); O = "What are the learning Outcomes" (Student's reflection individually as well as a group in changes of performance level on the ten (10) dimensions from the actual to desired level)

The MLA mentoring environment is anchored on the social interaction theory of Vygotsky²⁰ which posits that "students working together in a group promotes dialogical interchange as they share alternative viewpoints, support each other's inquiry processes, provide the right amount of support or assistance to accomplish a task he cannot accomplish independently. Gap of *current skills* and *desired skill* level is bridged as peers of learners cooperate and collaborate to enrich the learning experiences. The theory asserts: (1) social interaction, which plays a fundamental role in the process of cognitive development which appears on the social level (inter-psychological) and later on the individual level (intra-psychological); (2) Zone of Proximal Development (ZPD) where learning occurs. The Vygotsky theory of social constructivism focused on the connections between people and the socio-cultural context in which they act and interact in shared experiences.¹⁸ Lave and Wenger¹⁹ call this a process of "legitimate peripheral participation".

The defined tasks for level II learners are assessment skills, Level III on intervention skills and Level IV on management skills across life span, all mentored in scaffolding style of instruction. Current skills (actual level of proficiency) are self-assessed prior to actual exposure using the 10 dimensions of caring activities. When the student nurse attempts to perform a skill alone, she/he may perform a certain level of proficiency yet not be proficient at it (considered by Vygotsky as actual level). The desired clinical learning skill is set between the faculty and student individually and between the levels within RLE group to set the shared nursing care goals for assigned patients/case load. Clinical learning outcome is measured before and after MLA exposure.

Mentoring using “scaffolding” of instruction is provided the entire RLE rotation (2 weeks duration, minimum of 40 hours student contact). The mentor balances evaluation with instruction and supervision. Multiple formative and summative evaluation methods are used to assess the student's clinical learning.

Figure 1 below illustrates the MLA environment.

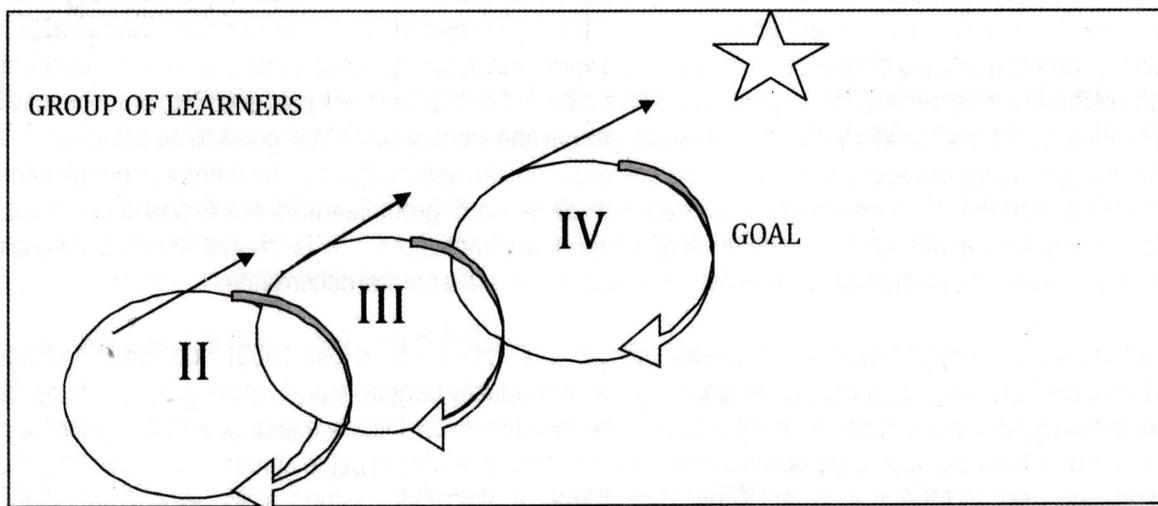


Figure 1. The spiral of MLA environment represents an openness in relationship depicting the inward, outward and forward thrust that characterize the student clinical development in the group learning process. The inward arrow of the spiral represents discovering self proficiency, indicates the direction of activity, toward self though not in isolation of other group of learners which may occur in dialogue. The outward-directed arrow represents building, sharing through dialogue. The group energy entails forward movement through time to meet the goal and commitment.

METHODS

Students assigned in the community and in the hospital were identified based on the schedule. Students who belonged to the deans' list, lowest 10% based on their major subject during the summer term, and those not belonging to any of the previous categories were clustered accordingly. Random samples were obtained from each stratum to form four groups composed of four second year, four third year, and four fourth year students. Two groups of 12 were formed in the community and another two groups in the hospital. The selection flow of subject selection is illustrated in Figure 1.

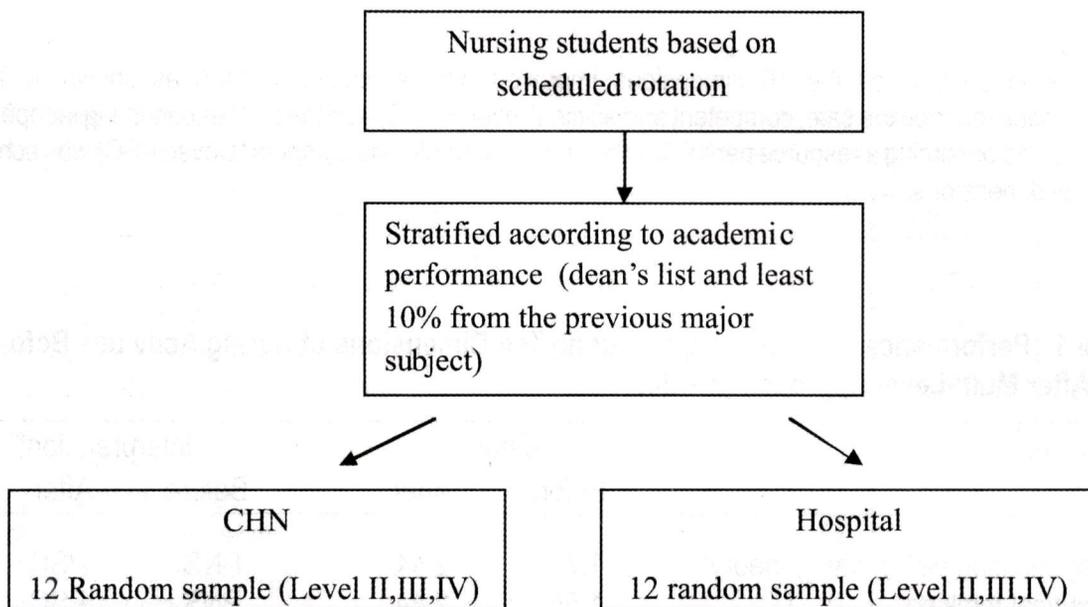


Figure 2. Selection flow of subject selection

Data Collection Process

Students were evaluated on the ten dimensions of nursing care before and after MLA using an instrument adapted from the competencies designed by the Board of Nursing of the Philippine Regulation Commission and content validated by a panel of experts. It generated data on the ten competencies in performing caring activities of the individual learner (I-CVI - .83). Determinants of a unified group were identified using a standardized self-evaluation checklist to find the extent of the interaction and involvement in group activities. The facilitators were asked pertinent questions by means of a guide to find out what they had learned from facilitating the group.

Data analysis

A multivariate analysis was employed to establish correlation between the variables described to reveal confounders that significantly affected the outcome of the study. The SPSS version 14 was used for statistical treatment. The intended outcomes evaluated included the clinical learning performance to evaluate the competencies gained from the multilevel approach along the ten dimensions of caring activities both hospital and community setting. Significant relationships and differences in outcome variables between and among groups were determined to test the hypotheses at the 0.05 level of significance.

RESULTS

Performance in all the 10 dimensions improved after exposure to MLA as shown in Table 1. *Communication* reached the safe, competent and efficient level (PSCE) with the learner becoming independent in most cases and becoming a resource person to other learners. A safe and competent level (PSC) was achieved in all the other dimensions.

Table 1. Performance Level of samples Along Ten Dimensions of Caring Activities Before and After Multi-Level Approach (n = 24)

Dimensions	Mean		Interpretation*	
	Before	After	Before	After
1. application with nursing theory	1.77	2.44	PNS	PSC
2. critical thinking	1.55	2.44	PNS	PSC
3. nursing process/therapeutics	1.65	2.41	PNS	PSC
4. competence in communication	1.62	2.60	PNS	PSCE
5. teaching-learning	1.85	2.50	PSC	PSC
6. scientific support	1.66	2.27	PNS	PSC
7. use of resources	1.89	2.50	PSC	PSC
8. group process skill	1.72	2.18	PNS	PSC
9. advances ethico-legal	1.54	2.20	PNS	PSC
10. accountability	1.60	2.27	PNS	PSC

LEGEND: *

1-1.7 : Performance not consistently safe (PNS) or accomplished within reasonable time frame, requires on going verbal and physical cues

1.8-2.5 : Performance is safe, competent (PSC) accomplished within reasonable time frame with minimal guidance

2.6-3.0 : Performance is safe, competent, efficient timeframe (PSCE), independent in most cases. Acts as resource to fellow learners

Table 2 shows the paired correlations of the caring activities of group of learners along the 10 dimensions. Moderate significant relationships on the dimensions of "advances ethico-legal" and "accountability", "teaching-learning", "nursing process/therapeutics", and "competence in communication" with were found after exposure to MLA. No significant relationships were found along the dimensions of application with nursing theory, critical thinking, scientific support, use of resources and group process skills among the group of learners.

Table 2. Paired Samples Correlations of Ten (10) Dimensions of Caring Activities Before and After MLA in Hospital and Community Setting (n = 24) at 0.05 level of significance

Dimensions	Df	Correlation	p value
Pair 1 c1 application with nursing theory	24	-0.184	0.389
Pair 2 c2 critical thinking	24	0.028	0.898
Pair 3 c3 nursing process/therapeutics	24	0.513	0.010
Pair 4 c4 competence in communication	24	0.414	0.044
Pair 5 c5 teaching-learning	24	0.522	0.009
Pair 6 c6 scientific support	24	0.369	0.076
Pair 7 c7 use of resources	24	0.178	0.405
Pair 8 c8 group process skills	24	0.356	0.087
Pair 9 c9 advances ethico-legal	24	0.523	0.009
Pair 10 c10 accountability	24	0.523	0.009

LEGEND:

* - significant at 0.05 level of significance

Table 3 shows the significant differences in all the dimensions of caring activities before and after exposure to the Multi-Level Approach. The null hypothesis of no significant difference in the performance level of learners along the 10 dimensions of caring activities after MLA exposure cannot be accepted at the 0.05 level of significance, suggesting that the MLA strategy demonstrated had effected changes in the dimensions of caring activities.

Table 3. Paired Samples t-Test of Significant Differences in Dimensions Before and After Exposure to MLA at the 0.05 level of significance (n=24)

Dimensions of caring activities	t	Df	p value
Pair 1 c1 application with nursing theory	-3.301	23	0.003*
Pair 2 c2 critical thinking	-4.239	23	<0.0001*
Pair 3 c3 nursing process/therapeutics	-3.245	23	0.004*
Pair 4 c4 competence in communication	-5.100	23	<0.0001*
Pair 5 c5 teaching-learning	-2.696	23	0.013*
Pair 6 c6 scientific support	-3.140	23	<0.005*
Pair 7 c7 use of resources	-4.453	23	0.000*
Pair 8 c8 group process skills	-3.444	23	0.002*
Pair 9 c9 advances ethico-legal	-2.584	23	0.017*
Pair 10 c10 accountability	-2.584	23	0.017*

LEGEND:

* - significant at 0.05 level of significance

Table 4 presents significant differences in the 10 dimensions of caring activities by setting. The t-test result for hospital setting revealed significant differences after MLA along nine dimensions. The null hypothesis could not be accepted. Results implied that the MLA as clinical instructional strategy significantly guided the learners and facilitator towards the enculturation of the novice learners within the hospital setting and onward to the achievement performance standard. Noteworthy are the results of significant differences in dimensions on “critical thinking”, “use of resources” and “communication” within the community setting.

Table 4. Paired Samples t-Test of Significant Differences in 10 Dimensions Before and After MLA by Setting at .05 level of significance

Dimension	t	df	p value	T	df	p value
Pair 1 c1 application with nursing theory	-3.079	11	0.010	-1.773	11	0.104
Pair 2 c2 critical thinking	-3.458	11	0.005	-2.590	11	0.025
Pair 3 c3 nursing process/therapeutics	-3.317	11	0.007	-1.483	11	0.166
Pair 4 c4 competence in communication	-3.527	11	0.005	-3.527	11	0.005
Pair 5 c5 teaching-learning	-2.602	11	0.025	-1.149	11	0.275
Pair 6 c6 scientific support	-2.966	11	0.013	-1.482	11	0.166
Pair 7 c7 use of resources	-4.005	11	0.002	-2.462	11	0.032
Pair 8 c8 group process skills	-3.447	11	0.005	-1.603	11	0.137
Pair 9 c9 advances ethico-legal	-1.773	11	0.104	-1.820	11	0.096
Pair 10 c10 accountability	-3.546	11	0.005	-.432	11	0.674

Table 5 shows significant differences at the 0.05 level of significance along five (5) dimensions out of the ten (10) dimensions namely: application with nursing theory, critical thinking, competence in communications, scientific support and advances ethico-legal activities. Results imply that the within and between group of learners, the performance level may vary along these caring activities as one moves in the clinical learning environment.

Table 5. Analysis of Variance (ANOVA) Test of Significant Differences in the Dimensions Within and Between Groups across setting

Groups	Sum of Squares	df	Mean Square	F	p value
C1 – Between Groups	0.563	6	0.094	11.250	0.009*
– Within Groups	0.042	5	0.008		
Total	0.604	11			
C2 – Between Groups	0.708	6	0.118	14.167	0.005*
– Within Groups	0.042	5	0.008		
Total	0.750	11			
C3 – Between Groups	0.974	6	0.162	19.479	0.003*
– Within Groups	0.042	5	0.008		
Total	1.016.	11			
C6 – Between Groups	0.375	6	0.062	7.500	0.021*
– Within Groups	0.042	5	0.008		
Total	0.417	11			
C9 – Between Groups	0.250	6	0.042	5.000	0.049*
– Within Groups	0.042	5	0.008		
Total	0.292	11			

Legend: * - statistically significant at 0.05 significance level

DISCUSSION

The process of designing an educational initiative centered around group of learners in the clinical setting often push an educator to reflect his or her assumptions about how learning is most effectively and efficiently harnessed within the group. The core group of faculty researchers believes that learning is a natural extension of an individual's interaction with group of learners within a meaningful learning environment. This process of learning continues through maturity. The MLA is founded on this belief grounded that it is dependent on environmental influences and social landscape of a learning context that creates the energy field and may facilitate what Bostock²⁰ called as "synergistic insights".

Our results showed that performance level of the samples of student learners improved after MLA was implemented. Performance along the ten dimensions of caring activities was enhanced from performance not consistently safe to one that is safe, competent and accomplished within reasonable time frame and minimal guidance from the faculty. Acquisition of the whole range of skill competency that the different levels of learners is expected to practice may have been influenced by the level of relationship within and between groups as it is through experience in the learning environment that meaning is constructed.²¹ Hansman and Wilson¹⁹ argued, however, that learning is ultimately shaped by the nature of the relationships learners establish between people and tools within this context.

Our results also showed a moderate correlation of approximately 0.50 or coefficient determination ($r^2 = 0.25$) indicating that 25% of variability between the paired sample correlation mean performance level of learners before and after the utilization of MLA along five dimensions (nursing process/therapeutics, competence in communication, teaching-learning, advances ethico-legal, and accountability) could be attributed to differences in two weeks-40 hour performance level across setting.

Our facilitators use the MLA approach as a strategy to teach the novice learners skills at their defined level of proficiency which they will eventually practice independently.²² Dialogue between the facilitator and the group of learners is central to the development of communication skill, group process skills and accountability as care provider. These skills are seen only when actions are observed.¹⁹

Our study showed significant differences in the performance level along the ten dimensions of caring activities after the exposure of learners to the MLA strategy across settings. The negative t-test results imply that the performance level was greater after MLA exposure. The difference in means did not occur by chance. The impact that the location/setting of clinical placement has on the student learner's confidence in communication, critical thinking, and use of resources was significantly better, when guided by an expert or peer and MLA strategy was utilized in both the hospital and community setting.

In summary, this study looked into the changes that occurred in the performance along the ten dimensions of caring activities of a group of learners with defined proficiency level after exposure to Multi-Level-Approach across clinical setting. We conclude that the Multilevel Approach (MLA) strategy in clinical supervision effected significant changes in enhancing performance level. Although the differences in performance level across setting was statistically significant, the clinical importance of five (5) dimensions not statistically significant namely, nursing process/therapeutics, teaching-learning, use of resources, group process skills and accountability needs looking into particularly because the sample size is small. The core faculty researchers had anticipated much larger span of dimension changes to reach the desired proficiency level. Although statistically significant, the performance progress of the group of learners is limited.

The MLA strategy is not a prescription for clinical instruction but rather should be used as a paradigm. There must be an infrastructure in place to support the 6 attributes of MLA. Both the learner and facilitator must be willing and motivated to engage in the learning process. If the six attributes are not met, the strategy/model will be compromised in its effectiveness. A follow-up research should also be done using an experimental design with increased sample size for possible structural modeling.

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Article 6

“NUTRI-CHIKA: Usapan Tungkol at Para sa Nutrisyon”: A Program Review

Georgina T. Paredes, MD, MPH; Jennifer M. Nales, MD, MSPH; Ramon Jason Javier, MD, FPAFP; Franciosa Luningning G. Gavino, MD, DPAFP; Jose Ronilo G. Juangco, MD, MPH; Grace E. Brizuela, MD, MSPH, FPCP

Department of Preventive and Community Medicine

ABSTRACT

Introduction/Objectives: Malnutrition among children is a prominent problem worldwide especially in the Philippines. Despite the notable decline in the wasting and stunting prevalence rates over the last two decades, the country still lags behind its Millennium Development Goal of reducing malnutrition prevalence to half by 2015. This program evaluation research emphasized the overall worth of a community-based nutrition intervention program, the “NUTRI-CHIKA: Usapan Tungkol at Para sa Nutrisyon” project, in improving the nutritional status of children. The program aimed to determine if an increase in the weight and height of the children participants could be attained by raising the level of basic nutrition knowledge of mothers and concomitantly giving the primary caregivers the opportunity to practice this knowledge through the meal planning, cooking, and feeding sessions.

Methods: A time-series design was used to evaluate the short and medium term outcomes, such as changes in knowledge scores of mothers and anthropometric measurements of their children through six months of the institution of the program.

Results: At the end of the program, an increase of almost a kilogram (5.63%) in mean weight was observed while positive net changes (4.56%) were seen in the height measurements for all age groups. Using multiple regression models, the independent variables (i.e. mothers' knowledge, child-related factors, and feeding-related factors) accounted for roughly 36% (R-square = 0.364) of all factors that affected the change in weight of the children while a much lesser value of approximately 33% (R-square = 0.329) could be attributed to the effects of the same independent variables on the observed changes in height.

Conclusion: The “NUTRI-CHIKA: Usapan Tungkol at Para sa Nutrisyon” Program influenced changes in height and weight, also reduced the proportion of malnourished children by 7% at the end of the 6-month program. Moreover, it also contributed to an increase in the mothers' nutrition knowledge scores especially at the end of the program.

KEY WORDS: community-based nutrition program; wasting and stunting; mother's knowledge; time-series program evaluation

INTRODUCTION

Malnutrition among children is a prominent problem worldwide especially in third world countries like the Philippines. In 2008, 3.35 million children age less than 5 years were found to be underweight, while 3.57 million were recorded as under-height or stunted⁽¹⁾. Despite the notable decline in the wasting (from 34.5% to 26.2%) and stunting prevalence rates (from 39.9% to 27.9) over the last two decades, the Philippines still lags behind its Millennium Development Goal (MDG) of reducing malnutrition prevalence to half by 2015⁽²⁾. Based on the completed 6th National Nutrition Survey, the -0.58 percentage point reduction rate of underweight among the under 5 years old children needs to be accelerated to equal or greater than 0.81 percentage point reduction for the country to achieve the MDG goal of 17.2% prevalence⁽³⁾. With this recommended reduction rate, the MDG may

still be achieved by year 2018. Thus, programs that address this concern need to be reviewed so that their impact and the efficiency of strategies and practices in program implementation can be adjusted for quality assurance and control. Nutrition program trials and reviews serve as guide and models in improving the quality of intervention programs. These studies enrich programs by taking into account the strengths and weakness in implementation. This will pave the way for a more efficient, cost-effective and cost-efficient interventions that will redound to the timely attainment of the country's MDG.

The beneficial effects of nutrition intervention programs among children have been reported in various studies^(4,5,6,7,8). However, approaches, strategies and methods of analysis varied, thus generating diverse results. Improvement in the level of nutrition knowledge of mothers positively and independently influenced the nutritional state of their children⁽⁷⁾. Furthermore, nutrition education of mothers coupled with supplementary feeding or the provision of complementary foods, led to a more notable increase in child growth^(6,8).

Overview of the "Nutri-Chika: Usapan Tungkol at Para sa Nutrisyon" Program

The UERMMMC College of Medicine established the Multi-Disciplinary Community Health Services Extension Program (MUCHSEP) in 2006⁽⁹⁾. Its objectives include the provision of health services through establishment of projects that address the priority needs of the target community. Initial community diagnosis report identified malnutrition as the prevailing concern among children in the target community. Worsened by the aftermath of typhoon Ondoy in October 2009, the malnutrition problem became more evident. In response to this worsening condition, the "Nutri-Chika: Usapan Tungkol at Para sa Nutrisyon" project was initiated and implemented by the MUCHSEP staff and post-graduate interns from the Department of Preventive and Community Medicine, representatives from the faculty of the institution's colleges, and the Dietary Section of the UERM Memorial Hospital. The project was also supported by a grant from various Philippine- and US-based alumni.

The processes followed in this program were based on the principles of community oriented primary care (COPC) by Kark⁽¹⁰⁾. Program development started with the examination of data gathered through community diagnosis. The prioritization process confirmed that malnutrition needed to be addressed. A blueprint was formulated, reviewed and implemented. This study examined the immediate and medium term outcomes of this community oriented nutrition program. Its heart was focused on empowering mothers of malnourished children, through improvement of the former's basic nutrition knowledge and practices by entrusting the responsibility of planning, preparing meals and feeding their malnourished children. All these transpired in a setting of an underserved and depressed community.

In the first quarter of 2010, a quick anthropometric survey was conducted to screen and identify the underweight children in Areas 29 and 38 Kapiligan in Barangay Doña Imelda, Quezon City, the adopted community of the medical center. The underweight children were classified into the various categories of malnutrition. The mothers of these children were oriented on their children's nutritional state, the proposed program expectations, mechanics, and desired outcomes. After interactive discussions on their corresponding responsibilities, consent to participate were elicited. Thirty-five children and their 20 mothers were initially enrolled to the program. The mothers were organized, their leaders elected, teams formed and given tasks. Among their responsibilities were the following: (1) participation in the nutrition education sessions, (2) preparation of the budget and meals, (3) doing the kitchen chores and (4) feeding the children. The teams managed the budget allocated, purchased the ingredients for the meals based on a booklet of prepared recipes patterned after the recommendations of the Food and Nutrition Research Institute⁽¹¹⁾. Six nutrition education sessions were conducted to improve knowledge related to proper nutrition. Pre-test and post-test scores

related to the subject matter were conducted during each education session. The actual preparation of meals and feeding sessions served as the venue for the application of proper nutrition practices. Regular meetings with the mothers threshed out problems. These opportunities allowed the detection of changes in their nutrition related practices. A nutrition diary was also accomplished for each of the mothers, through interviews conducted by the post-graduate interns assigned to each subject enrolled in the nutrition program.

Meanwhile, the malnourished children were given supplementary lunch meals four times a week during the initial two-month intensive phase. This was followed by three times per week supplemental lunch meals for the succeeding four months. One glass of fresh milk with each lunch meal was also served. Weight and height were measured at the start and every four weeks during the feeding months. The proportion of the food consumed by each child every feeding, reports of acute illness and attendance to feeding were noted every session.

This program evaluation research emphasized the overall worth of this nutrition intervention program. More importantly, program administrators and planners may gain insights for the improvement or modification of the program's processes. Specifically, the program aimed to determine if an increase in the weight and height of the children participants could be attained by raising the level of basic nutrition knowledge of mothers and concomitantly giving the primary care-givers the opportunity to practice this knowledge through the meal planning, cooking, and feeding sessions in the hope that these would lead to improving their nutrition related practices and ultimately, the nutrition status of their children.

METHODS

Study Design

This is a program review of the "NUTRI-CHIKA: Usapan Tungkol at Para sa Nutrisyon" project. Time-series design was used to evaluate the short and medium term outcomes like, such as (1) changes in knowledge scores of mothers and (2) anthropometric measurements of their children. The weight and height of the children were regularly followed up at 4-week intervals. During feeding sessions, attendance and proportion of meals consumed by the children were recorded. Pre-test and post-test knowledge scores of the mothers were compared after each of six nutrition education sessions. A comprehensive test, in the form of a modified objective structured clinical examination (OSCE), was given at the end of the program. During the course of the feeding, mothers practiced meal budgeting, cooking nutritious recipes, proper hygiene, food sanitation, and actual feeding of the children.

Subjects

The program participants initially consisted of 30 underweight children with their respective 20 mothers identified during a malnutrition screening program.

The Basic Nutrition Education Curriculum

Six case-based, interactive modules were designed to convey important basic nutrition messages. Topics covered during the interactive modules were: (1) Basic Nutrition; (2) Food-Borne Illnesses; (3) Proper Food Handling and Storage/Proper Food Preparation; (4) Food Substitutes; (5) Food Myths; and (6) Monitoring Growth of Children. These were delivered on a weekly by nutrition expert facilitators, including faculty members from the Colleges of Medicine and Nursing and the Dietary Section of the UERM Memorial Hospital.

Data Collection

Knowledge level on each topic was tested among mother participants before and after the education sessions with a 10-15 multiple choice question instrument. The trend throughout the six month period and the overall net changes in percentage were derived. Moreover, a comprehensive examination was done at the end of the sixth month. This was conducted via a modified objective structured clinical evaluation (OSCE), consisting of 11 stations. Properly oriented Community Medicine interns measured the height and weight of the children at the specified times using a standardized Makida ZT 120 Health Scale. Weight-for-age and height-for-age were classified according to the Food and Nutrition Research Institute recommendations and standards⁽¹⁰⁾ as follows: (1) normal, (2) below normal, and (3) very low normal, according to gender. This standard was based on the International Reference Standards (IRS), NCHS/WHO, 2007, where measurements in the standard population falling between +1.00 to -1.00 standard deviation (SD) from the mean are considered within normal, between -2.00 to -2.99 SD as underweight, stunted or acutely wasted, -3.00 SD and lower as severely underweight, severely stunted, severe wasting categories. These categories could also occur solely or in combination in a particular subject. Data on the amount of food consumed per feeding per child, number of absences during feedings and other demographic information were collected. Visual observation and estimate on the amount of food (in %) consumed by each child every after feeding were recorded by the assigned intern with random supervision by the principal and supervising investigators.

Data Processing and Analysis

Data were encoded using MS Excel and processed using Statistical Package for Social Sciences (SPSS) version 14. Mean weight and height measurements were plotted through time. The proportion pulled out of malnourished states was estimated at the end of the feeding program. Net changes (%) in weight and height were estimated. Descriptive statistics were derived for the appropriate variables like the average amount of food consumption (%) per meal and milk servings, the average number of absences from the feeding sessions, and reports of illnesses during the entire duration of the program.

The mothers' net score changes were computed based on average knowledge test scores before and after each education session and the comprehensive examination score. These and other independent variables pertinent to the children and the supplemental feedings were considered in the regression equation. The regression analysis enabled the identification of variables related to the outcome, and the quantity of their contribution to the weight and height changes. Beta coefficients and R-square values including adjusted R-square were derived to show presence and direction of relationships between the variables. The latter gave an estimate of the contribution the variables exerted on the changes in weight and height.

RESULTS

The Subjects: Mothers and Children

The profile of the mothers showed a preponderance of high school-educated subjects. There was a mix of young and middle-aged mother participants (range = 28-43 years), with a mean age of 35.3 years (SD = 4.09). Six of the 20 mothers had two or more children enrolled in this program. All of them were informal settlers in Areas 29 and 38 Kapiligan, Barangay Doña Imelda, Quezon City. Two mothers (10%) and five children (16%) dropped-out of the study after they moved out of the area, leaving 18 mothers and 25 children. The range of values for weight and height included values that were below normal for the age category. The mean anthropometric values did not follow the standard trend by gender (Table 1). The values among the boys were usually expected to be higher compared to females but not in the series (Table 2).

Table 1. Age distribution, weight and height measurements of the feeding program participants: all children (N = 25) pre-feeding

Age (in mos) Distribution	N	Mean Weight in kgs. (SD)	Range of Weights	Mean Height in cms. (SD)	Range of Heights
≤36	7	9.57 (1.13)	9.00-12.00	78.71 (2.21)	75.0-81.0
37-48	4	12.32 (0.52)	12.00-13.10	90.62 (5.37)	84.0-96.5
49-60	6	14.00 (2.28)	10.00-17.00	96.08 (5.42)	89.0-105.0
≥61	8	15.38 (2.44)	13.00-19.00	102.00 (3.44)	96.5-104.0
All ages	25	12.93 (2.97)	9.00-19.00	92.24 (10.18)	75.0-104.0

Table 2. Mean weight (kgs) and height (cms) distribution by gender and age groups of children.

AGE GROUPS (in mos)	BOYS		GIRLS	
	Mean WEIGHT (SD)	Mean HEIGHT (SD)	Mean WEIGHT (SD)	Mean HEIGHT (SD)
≤36	11.0 (1.4)	78.0 (4.2)	9.0 (0)	79.0 (1.6)
37-48	12.0 (0)	89.0 (0)	12.4 (0.6)	91.2 (6.4)
49-60	15.0 (1.4)	98.4 (4.9)	12.0 (2.8)	91.5 (3.5)
≥61	15.2 (2.3)	103.0 (3.3)	15.7 (3.2)	100.3 (3.5)
ALL AGES	14.2 (2.4)	96.1 (9.7)	11.8 (3.1)	88.7 (9.3)

Short and Medium Term Program Outcomes: Changes in Knowledge Scores of Mothers and Anthropometric Measurements among Children

The net change in the knowledge level of the mothers, measured as the percentage difference between mean pre-test and post-test ratings of mother-subjects on each education session was sizable. However, a decline of approximately 6.0% was noted between the post-test and the comprehensive examination (OSCE) rating given at the end of six months (Table 3). The net changes in weight and height for the duration of the project were modest. An increase of almost a kilogram (5.63%) in mean weight was observed. Moreover, positive net changes (4.56%) were seen in the height measurements for all age groups (Table 4).

Table 3. Summary of test scores of mother-participants.

	Average Number of Mother Examinees	Mean Test Ratings (SD)
Pre-Test Scores (6 sessions)	13	79.83
Post-Test Scores (6 sessions)	12	93.59
Percentage Change in Pre-Test and Post-Test Scores	—	+17.0%
Comprehensive Test / OSCE Scores	19	87.78

Table 4. Summary of net changes in weight and height of the children for the duration of the project.

Age Groups (in mos)	% Change in Weight	% Change in Weight	% Net Change in Weight	% Change in Height	% Change in Height	% Net Change in Height
	BOYS	GIRLS		BOYS	GIRLS	
≤ 36	6.82	16.67	13.43	6.41	5.57	5.80
37-48	8.33	11.26	10.55	2.25	4.94	4.27
49-60	1.67	12.50	4.77	4.45	7.65	5.46
≥ 61	5.26	(-8.51)	0.06	3.20	3.24	3.22
All ages	4.41	6.98	5.63	3.99	5.14	4.56

The influence and the direction exerted by the independent variables on the anthropometric measurement changes were analyzed using multiple regression models. The education sessions and the complementary feeding were considered in the regression model. Examination of the beta coefficients revealed that the observed change in weight for every unit change in the independent variable was found to be negative for the mothers' post-test ratings and the children's attendance at feeding sessions. For height change, the mothers' knowledge post-test ratings, amount of food consumption, and age of the children negatively influenced height variation (Table 5). The total amount of influence exerted by all the independent variables under consideration accounted for roughly 36% (R-square = 0.364) of all factors that affected the change in weight of the children. On the other hand, a much lesser value of approximately 33% (R-square = 0.329) could be attributed to the effects of the same independent variables on the observed changes in height (Table 6).

Table 5. The regression model summarizes the influence and the direction exerted by the independent variables on the anthropometric measurement changes of the study subjects.

Independent Variables	Weight Change	Height Change
	Standardized Coefficients Beta	Standardized Coefficients Beta
Mothers' Knowledge:		
• Post-Test Scores	-0.125	-0.368
• Comprehensive Test	0.342	0.374
Children Related Variables:		
• Age	0.266	-0.199
• Gender	0.294	0.449
Feeding Related Variables:		
• % Food Consumption	0.310	-0.005
• Attendance at Feeding Sessions	-0.656	0.259

Table 6. The model summary shows the R-square and adjusted R-square for the changes in the weight and height of the study subjects.

MODEL	WEIGHT CHANGE		HEIGHT CHANGE	
	R Square	Adjusted R Square	R Square	Adjusted R Square
Predictors: ALL INDEPENDENT VARIABLES	0.364	0.110	0.329	0.061
ALL FEEDING AND CHILD RELATED VARIABLES	0.227	0.073	0.092	-0.090
• age, gender, attendance during feeding sessions	0.112	-0.015	0.087	0.043
• age and percentage of food consumption	0.173	0.098	0.059	-0.026
• food consumption amount	0.126	0.088	0.008	-0.035
ALL MOTHER RELATED VARIABLES	0.051	-0.049	0.123	0.031
• post test score	0.021	-0.023	0.018	0.027
• comprehensive / OSCE score	0.019	-0.030	0.078	0.032

DISCUSSION

Published studies on the effectiveness of complementary or supplemental feedings with or without concomitant nutrition counseling among mothers of the targeted malnourished children have depicted significant changes in weight and growth of the target children^(4,5,6,7,8). An increase in nutrition related knowledge of mothers is likewise related to nutrition education and training alone. More promising results, like an extra gain in weight and height resulted from the combination of nutrition counseling and provision of complementary feeding in 17 pooled studies⁽⁶⁾. Varying designs, ranging from randomized controlled trials to program reviews or evaluation, showed that nutrition intervention produced mixed results but mostly positive. In some situations, negative changes in specific output were noted⁽⁵⁾.

The Community Nutrition Education Logic Model⁽¹²⁾ suggests other subject areas suitable for review. These include an evaluation on program inputs (i.e. resources and the planning process) and program outputs (i.e. activities and subject participation, and ultimately, the short, medium and long term impact).

Nutrition Education and Knowledge Gained by Mothers

A study conducted in Ghana showed that mothers who underwent nutrition education raised children with better nutritional status. This nutrition knowledge independently and significantly influenced their children's nutritional status even in the setting of poverty and low level formal education⁽⁷⁾. The quality of care for children provided by the mothers was significantly related to the level of nutrition knowledge and practices, especially those obtained from a program that focused on nutrition education^(6,12,13). The effects on nutrition status however, may be positive or negative, and was dependent on the attitude and practices on caring for the child⁽¹³⁾. The review done by Dewey et al on nutrition education on complementary feeding likewise showed a modest effect on the weight and growth of children⁽¹⁴⁾.

Nutrition Education of Mothers, Meal and Milk Supplementation and Children's Weight and Height

The improvement in the nutritional status of 18 of the 25 children is a testament to the effects of this 6-month intervention program. At the end of the program, the proportion of malnourished children improved from 96% to 89% while 86% experienced only a shift to a better malnutrition category. This finding is consistent with various studies and programs which recorded modest changes as well^(14,15). Pooled effect mean differences in weight of 0.25 kg and 0.54 cm in height for both education and complementary feeding interventions were observed in selected third world settings in studies analyzed by Imdad et al⁽⁶⁾. A decline in prevalence of malnutrition from 66.4% to 28.3% was similarly observed in Senegal over a six-month intervention program⁽⁸⁾. Furthermore, when nutrition education alone was conducted, pooled effect mean difference in weight was estimated at 0.30 kg and 0.49 cm in height gain⁽⁶⁾.

The Philippine National Nutrition Surveys from 1990 to 2001 recorded a decrease in underweight prevalence of 34.5% to 30.6% or a 12% net change according to FNRI periodic state of nutrition report⁽²⁾. The NUTRI-CHIKA feeding program recorded an absolute change in mean weight of 0.33 kg (-2%) and 4.2 cms (4.56%) in mean height for the entire duration of the program. The changes experienced in this study follow the patterns observed in other settings.

Biases are not unusual in research and program implementation^(4,7,8). The effect of maturation in this one-group, time-series design could not be discounted. There were obvious inter-observer biases committed during anthropometric measurements and in the estimates of food consumption of the participants. These sources of bias, plus other implementation weaknesses, might have contributed to the observed non-directional changes. These, unfortunately, had not been factored in the present analysis. Thus, the need for a process evaluation is apparent.

Nutrition education of mothers, with supplemental feeding even in the form of one meal and a glass of milk given three to four times a week for a duration of six months matter. The "NUTRI-CHIKA: Usapan Tungkol at Para sa Nutrisyon" Program influenced changes in height and weight, also reduced the proportion of malnourished children by 7% at the end of the program. Moreover, it also contributed to an increase in the mothers' nutrition knowledge scores. The mothers' nutrition education, the supplemental feeding and children related variables under study accounted for only 36% of the resulting changes in weight and about 33% for height. Meal and milk supplementation and child related variables contributed the most in the regression equation. Although biases were not totally avoided in the course of the measurement, the results reinforced findings from previous studies that nutrition education with supplemental feeding contributed to child growth and development.

A process evaluation needs to be done. This will benefit program implementers by providing evidence-based improvement for the program. A better program can ultimately redound to better nutritional state among children in this community.

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Article 7

Parents' Profile and Level of Early Intervention Physical Therapy Services Rendered to Children with Physical Disabilities

Esther Melody R. Nicolas, PTRP, MAEd, Irene T. Acuna, MEd

Graduate School

ABSTRACT

Introduction/Objectives: Family-centered approach to early intervention which is a part of special education has been recognized through the Republic Act (RA) 8980, known as the Early Childhood Care and Development Act. This study aimed to determine the perceptions of parents on family-centered early intervention physical therapy services for children with physical disabilities, and their relationship with the parents' profile.

Methods: The study was conducted among parents of children six years old and below undergoing physical therapy services in Quezon City. The Measure of Processes of Care (MPOC-20) was used to measure parents' perceptions on the behaviors of their early intervention physical therapists and the staff of the institution where they receive the services. It has four domains, namely: providing information, enabling partnership, respectful and supportive care, and comprehensive and coordinated care.

Results: Thirteen parents qualified and participated in the study. Based on the means of the MPOC-20, parents perceived a family-centered physical therapy approach. However, they had lower scores compared with the previous literature. The study also revealed that there was no significant relationship between the parents' socioeconomic status and the level of early intervention physical therapy services on all domains of the MPOC-20.

Conclusion/Recommendations: A consistent family-centered practice during early intervention is recommended for physical therapists and rehabilitation centers. Standardized programs that will further its use for children with disabilities is also suggested.

KEYWORDS: MPOC-20, family-centered early intervention

INTRODUCTION

One of the concerns of those who work with young children with special needs is early intervention defined as the provision of services, including physical therapy, occupational therapy, speech therapy, and/or educational services to children with developmental disabilities.¹

The United States has mandated the provision of early intervention among infants and toddlers with physical disabilities through the Disabilities Education Act (IDEA) Part C which is explicitly family-centered. In the Philippines, the provision of early intervention services as a government policy is anchored on government agencies, namely the Department of Health (DOH) and the Department of Education (DepEd). It is aimed towards the prevention of occurrence and progression of disability among infants and children below six years old and early rehabilitation and education services for the young child found to have a risk of having disability or developmental delay. RA 7277/RA 9442, the Magna Carta for Disabled Persons, provides for the rehabilitation, self-development and self-reliance of persons with disabilities (PWDs) and their integration into the mainstream of society. The Special Education (SPED) Act of 2004 aims to provide information to parents about the full

continuum of services and equip them, other caregivers and teachers with capabilities to identify, prevent, refer and intervene with the disabilities of children. Enhancing the role of parents and other caregivers is also offered under this law. RA 8980 or the Early Childhood Care and Development (ECCD) Act, promulgates a comprehensive policy and a national system for early childhood care and development (ECCD). It enhances the role of parents as the primary caregivers, other caregivers and educators of their children.

Despite these laws, provisions for a family-centered approach on early intervention services have not been specified, unlike in other countries where family-centered early intervention programs have been established. This situation directed the researcher to the questions: Are family-centered practices observed during an early intervention program, particularly physical therapy services, among children with physical disabilities? If so, how does parents' profile affect the level of physical therapy services during early intervention? Thus, this study was undertaken to determine whether there is a relationship between the parents' profile and level of early intervention physical therapy services among children with physical disabilities.

METHODS

This study utilized a correlative research design. The respondents were limited to parents who had children six years old or younger with physical disabilities, who have been receiving early intervention physical therapy services for at least one year, starting 2003. The study was conducted at the Philippine Children's Medical Center (PCMC) and the Stimulation Therapeutic Activity Center (STAC) in Quezon City. Physical therapists from these two centers were asked to identify children undergoing physical therapy services in their centers that were age six years and below. Purposive sampling was used.

Two questionnaires were used in this research. The first questionnaire was a researcher-made survey form to profile of the parent-respondents and the children receiving early intervention physical therapy services. The second questionnaire was a standardized tool, the Measure of Processes of Care (MPOC-20), developed by the CanChild Centre for Childhood Disability Research at McMaster University (ON, Canada). It measured the perceptions of the participants about their physical therapist and the organization providing early intervention physical therapy services to their child. Perceptions gathered were along four domains: (1) providing information (2) enabling and partnership and (3) respectful and supportive care, and (4) comprehensive and coordinated care. To ensure that the respondents had a clear understanding of the items, the questionnaire was translated to Filipino by a professor in Filipino of University of the East Ramon Magsaysay Memorial Medical Center, Inc. The correlation between the independent and dependent variables was then measured.

RESULTS

Respondents' profile

Thirty-three children-patients screened, but only 13 were eligible; the rest were excluded for receiving physical therapy services for less than a year. The parents of all 13 children consented to participate in the study. The children, aged 9 months to 6 years, consisted of 8 girls and 5 boys as seen in Table 1. The most common disabilities were cerebral palsy (61.5%) and muscular dystrophy (15%); no child had multiple disabilities. Symptoms were noted in half of the children between three and 9 months. Only one (7.7%) parent claimed that a developmental problem was noted in his child before birth. Most of the children were diagnosed at about the same age their parents noticed the symptoms. More than half of the children (54%)

underwent physical therapy at the Physical Medicine and Rehabilitation Department of PCMC. Most (77%) of the children underwent physical therapy sessions twice a week and the rest had sessions three times a week.

Table 1. Profile of children with physical disabilities.

Variables	Frequency	Percentage
Age (months)		
0-3	-	-
3-6	-	-
6-9	-	-
9-12	4	30.8
12-24 (1-2 years)	4	30.8
24-48 (2-4 years)	4	30.8
48-72 (4-6 years)	1	7.7
Gender		
Male	5	38.5
Female	8	61.5
Diagnosis		
Cerebral Palsy	8	61.5
Spina Bfida	1	7.7
Muscular dystrophy	2	15.4
Multiple disabilities	-	-
Others	2	15.4
Age when symptoms of impairment or disability were noticed (months)		
0-3	1	7.7
3-6	4	30.8
6-9	3	23.1
9-12	2	15.4
12-24 (1-2 years)	2	15.4
24-48 (2-4 years)	-	-
48-72 (4-6 years)	1	7.7
Age diagnosed with disability or impairment (months)		
0-3	1	7.7
3-6	3	23.1
6-9	3	23.1
9-12	3	23.1
12-24 (1-2 years)	2	15.4
24-48 (2-4 years)	-	-
48-72 (4-6 years)	1	7.7
Early intervention physical therapy setting		
Physical Medicine & Rehabilitation Center	7	53.8
Community Based Rehabilitation	6	46.2
Frequency of physical therapy session		
Daily	-	-
Twice a week	10	76.9
Three times a week	3	23.1

Most of the 13 parents (77%) were mothers, of which 10 were housewives. Five of the parents were college graduates; the rest reached at least high school. 77% had monthly incomes of P15,000 or less. More than 2/3 had one or two children and came from urban areas. Eight children lived with both parents. The parents' profile is presented in Table 2.

Table 2. Profile of the parents.

Variables	Frequency	Percentage
Occupation		
housewife	10	76.9
business	2	15.4
teacher	1	7.7
Level of Education		
some high school	2	15.4
completed high school	4	30.8
some technical training	-	-
some college	2	15.4
completed college	5	38.5
graduate school	-	-
Family Income		
Php 0-7,000	6	46.2
Php 7,000-15,000	4	30.8
Ph 15,000-25,000	3	23.1
Php 25,000-50,000	-	-
>Php 50,000	-	-
Number of children in the family		
1-2	8	69.2
3-4	3	23.1
5-6	1	7.7
Type of community		
Rural	4	30.8
Urban	9	69.2
Family Type		
single parent	2	15.4
two parents	8	61.5
extended family	3	23.1

Level of Early Intervention Physical Therapy Services as Perceived by Parents

Providing information. Table 3 shows that providing information about the results of assessments had the highest mean score (6.85), whereas making available to the parent information in various forms, such as a booklet, kit, video, etc. had the lowest mean score (1.38).

Table 3. Perceived level of early intervention services provided.

Domains of Care and Services Rendered	Mean	Descriptive Interpretation
Providing Information		
Provided by people		
- written information about what the child is doing in therapy	2.08	Very small extent
- written information about the child's progress	2.08	Very small extent
- results from assessments	6.85	Great extent
Provided by the organization		
- types of services offered at the organization in the community	5.92	Fairly great extent
- information on the child/s disability	6.23	Great extent
- opportunities for the entire family to obtain information	3.00	Small extent
- booklet, kit, video, etc	1.38	Not at all
- advice on how to get information or to contact other parents	1.92	Not at all
Enabling partnership		
- choose when to receive information and the type of information wanted	5.31	Fairly great extent
- fully explain treatment choices	5.31	Fairly great extent
- provide enough time to talk so the parent don't feel rushed	6.92	Great extent
Respectful and supportive care		
- look at the needs of the whole child	6.38	Great extent
- make sure that at least one team member is someone who works with the parent and family over a long period of time	6.54	Great extent
- plan together so all are working in the same direction	1.31	Not at all
- give information about the child that is consistent from person to person	6.69	Great extent
Comprehensive and coordinated care		
- help to feel competent as a parent	6.77	Great extent
- provide a caring atmosphere rather than just give information	6.54	Great extent
- provide opportunities to make decisions about treatment	2.38	Very small extent
- treat as equal rather than just as the parent of a patient	6.85	Great extent
- treat as an individual rather than as "typical" parent of a child with a disability	8.77	Great extent

Enabling partnership. Results showed that the provision of time for parents to talk with the therapists was provided to a great extent (score of 6.92). They also were given full explanation on the treatment choices for their child and were allowed to choose when to receive information and the type of information they wanted to a fairly great extent (score of 5.31).

Respectful and supportive care. As a whole, parents felt that they were respected to a great extent by the physical therapists who treated their child. However, most parents claimed that they were not involved in planning their child's intervention.

Comprehensive and coordinated care. The findings showed that equal services were provided to the disabled children to a great extent, except for the fact most of them were not given the chance to make decisions for their child; thus, there was no coordinated care. Some parents reported that they were not aware that they could make decisions for their child.

The mean scores on the MPOC-20 domains ranged from 3.69 to 5.86. *Comprehensive and coordinated care* had the highest mean score (5.86) followed by *Enabling Partnership* (5.85), and *Respectful and Supportive Care* (5.23). On the other hand, *Providing Information* had the lowest mean score (3.69). A summary of the descriptive data for the means of the MPOC-20 domains are presented in Table 4. The mean scores ranged from 3.69 to 5.86 (7 = to a great extent).

Table 4. Summary of means of level of early intervention services.

Domains of Processes of Care	Mean	Descriptive
Providing Information	3.69	Small extent
Enabling Partnership	5.85	Fairly great extent
Respectful and Supportive Care	5.23	Fairly great extent
Comprehensive and Coordinated Care	5.86	Fairly great extent

Relationship between Parents' Profile and Perceived Level of Early Intervention Physical Therapy Services

Table 5 shows the correlation between the parents' profile and their perception of early intervention physical therapy services. It shows that most of the parents' profile variables were not significantly correlated with early intervention physical therapy services except for occupation with *Providing Information* which showed moderate correlation. There was no significant correlation for the other variables.

Table 5. Correlation matrix of the respondents' profile and perceived level of early intervention physical therapy services.

Variables	PI <i>r</i>	EP <i>r</i>	RSC <i>r</i>	CCC <i>r</i>
Occupation	.500	.334	.230	.232
Level of Education	-.093	-.149	-.019	.112
Family Income	-.158	-.071	-.284	.054
Number of children	.337	-.019	.304	.035
Type of Community	.299	.151	.159	.024
Family Type	-.279	-.260	-.417	.206

Legend: $p < 0.05$; PI- Providing information; EP- Enabling Partnership; RSC- Respectful and supportive care; CCC- Comprehensive and coordinated care

DISCUSSION

The children in this study were diagnosed early since they were given medical attention at the same age when their symptoms of physical disability were noticed, indicating that most of the parents did not delay seeking medical help for their children. This result affirms the principle of early detection. Early detection leads to early intervention which helps alleviate the symptoms especially within the sensitive period which is the time when the child is more responsive to specific forms of experiences. Therefore, positive outcomes in the child are expected. No child younger than 9 months received early intervention physical therapy services, suggesting that further dissemination of information about early detection and intervention to parents should be emphasized. Most of the children were observed by their parents to have symptoms of disability at the age of three to six months. This finding implies that promoting newborn screening system for certain conditions is important to avoid late detection of a developmental problem.

Most parents had low income levels but despite this, the parents still availed of physical therapy services for their disabled children. Majority of the respondents lived with their spouses and their children, or had an extended family. The availability of the parents or other adults in the family for the child undergoing physical therapy is an important factor in the success of a family-centered intervention.

The mean scores on the MPOC-20 domains were lower than those reported by O'Neil et al.² High scores were obtained for *Comprehensive and Coordinated Care*, followed by *Enabling Partnership and Respectful and Supportive Care*. In spite of their not being involved in planning the interventions, the parents perceived that their children received family-centered early intervention physical therapy services to the greatest level in these three areas.

Our findings also suggest the need for physical therapists and the organization to give written information constantly to parents based on the low scores for the MPOC domain on *Providing Information*. The parents felt that they needed more information regarding the therapy and condition of their child. Written information regarding the progress and treatment plan for the child will help them monitor their child's needs. This finding is consistent with those of O'Neil et al.² and Raghavendra et al.³

In analyzing the correlation between the parents' profile and their perception of early intervention physical therapy services, most of the parents' profile variables did correlate with early intervention physical therapy services except for *occupation with Providing Information* which showed moderate correlation. This implies that parents in the study receive the services regardless of their education background, financial status, number of children, family type and residential status.

Parents who had an occupation received better early intervention physical therapy services related to *Enabling Partnership, Comprehensive and Coordinated Care* and *Respectful and Supportive Care*, but only to a small extent. The level of education of the parents did not significantly affect the behaviors of their physical therapists towards them during early intervention. This finding is in contrast with the results of the study of Bailey et al.⁴ on first experiences with early intervention in which level of education of parents and caregivers showed a linear relationship to the quality of experience entering early intervention. The financial status of the parents did not show significant relationship with the extent of physical therapy services during early intervention. This finding is different from that of Bailey et al.⁴ which revealed that families with low household income level received more negative experiences during early intervention. The type of community also had no significant relationship with *Providing Information, Enabling Partnership, Respectful and Supportive Care*, and *Comprehensive and Coordinated Care*, in contrast to the study of Raghavendra et al.³

In summary, our study showed that children with disabilities in the study who were undergoing rehabilitation generally received a family-centered early intervention physical therapy service. The parents felt that the physical therapy care that their children receive was holistic, continuous and consistent over time, settings and people. However, there was insufficient information provided to them by the physical therapists and the organization that provided the service. This points to a deficiency in the relationship between the parents and the rehabilitation service providers. As a whole, parents' profile had no significant relationship with the level of early intervention physical therapy services as to their perceptions. This is a favorable indication that their socioeconomic status does not affect the services that the children receive.

Based on these findings, there is a need for a standardized program in pediatric rehabilitation during early intervention which will promote family-centered care. In a way, incorporating family-centered approach of pediatric care in the curriculum of physical therapy program will help prepare the students in their future role as professionals in the field of early intervention. Physical therapists are encouraged to enhance their management strategies for pediatric patients. This includes providing written information to the parents about the therapy of their child, its progress and results of assessments. Planning together with the parents is also encouraged. Asking them about their goals, interests and priorities about their child and increasing their role in the program will make them feel that they are the experts of their child.

Rehabilitation centers are also encouraged to disseminate information to parents on the types of services they offer, provide booklets, kits or videos, give opportunities for the entire family to obtain information about the disability of their child, and provide advice on how to get information or to contact parents' organization. Providing information should be independent from the occupation status of a parent. Physical therapists are encouraged to provide equal amount of care as to giving information to the parents of children with disabilities.

A larger sample size is also recommended to obtain more precise results. Children with physical disability who are receiving early intervention physical therapy services for less than a year can be included in future studies to increase the sample size. Future researchers are advised to conduct a qualitative study on the experiences of parents during early intervention program. This will further reveal specific sentiments of the parents about the physical therapy of their child. In addition, a study which will include direct observation of physical therapists' behaviors during early intervention is recommended. A study which will compare the outcomes of a family-centered physical therapy with a patient-centered physical therapy during early intervention will also be useful.

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Article 8

Qi Gong Therapy and the Perceived Level of Stress of Level II Student Nurses

Mark Joseph Javier, Steffi Anne Manzano, Mary Ann Mejia, Kimberly Marie Melcoton, Danica Mae Mendoza, Ma. Elizette Monastrial, Cora Christine Quinto, Samuel Ramos III, Patrick Raval

College of Nursing

ABSTRACT

Introduction/Objectives: There had been a number of researches that investigated the stress management techniques of college students. The objective of this study was to determine whether Qi Gong as an intervention would aid in the reduction of the level of stress among undergraduate nursing students in a college of nursing.

Methods: In order to assess the level of stress of the participants, the investigators used the Perceived Stress Scale (PSS). Qi Gong Therapy was used to reduce level of stress.

Results: The findings revealed that Qi Gong Therapy did not have a significant effect on the reduction of stress levels among nursing students. The means score of the control group during the pre- and post-survey showed an insignificant decrease in the level of stress. The mean score of the treatment group, on the other hand, showed a decrease on the level of stress but was not statistically significant.

Conclusion: Qi Gong intervention did not cause significant decrease in the level of stress after the intervention. There was a decrease in the level of stress among the nurses given Qi Gong, though not statistically significant, which could be probably due to the length of time and the number of times Qi Gong intervention was conducted. The investigators recommend that a future study where the duration of time and frequency of Qi Gong intervention is increased.

KEY WORDS: Qi Gong, student nurses, stress

INTRODUCTION

Stress is an emotional and physical reaction to change common to every individual. It is experienced in varying degrees and can either be beneficial or harmful. In small doses, stress may increase an individual's energy, alertness and it even help focus on problems at hand but when stress becomes too great, it surpasses one's ability to cope in a positive way.¹

Both the external and the internal factors that affect the individual are common sources of stress. The physical environment including an individual's career, relationships with others, home life, and situations, challenges, and expectations an individual encounters on a daily basis are external factors of stress. Internal factors of stress influence the ability to cope with external stress-inducing factors which include the nutritional status, overall health and fitness levels, emotional well-being, and the amount of sleep and rest of an individual.² Similar to students in many other fields, students under the nursing program face the same sources of stress. Failure to resolve student stress for a longer period of time could lead to serious professional and personal problems, such as failing grades

and poor academic performance³. Individuals deal with stress through several methods such as removing the stressor by changing the environment, developing specific responses to help deal with the stressor or diverting their attention from the stressor⁴ such as engaging in regular exercise.⁵

An emerging form of exercise that is yet to be proven effective in reducing stress is Qi Gong which is an old Chinese practice dating back approximately 2,500 years ago and is believed to be a powerful system of healing and energy medicine.⁶ The increasing interest on Qi Gong at present and its potential to decrease stress level led the investigators to conduct a study about the said practice.

The primary objective of this study was to determine whether Qi Gong as an intervention would aid in the reduction of the level of stress among undergraduate nursing students of UERMMMCI College of Nursing. This study aimed to help nursing students cope with their stressors and at the same time reduce their levels of stress to maintain equilibrium between them and the environment.

METHODS

This was a quasi-experimental non-equivalent pretest-posttest time series quantitative study. Included in the study were currently enrolled nursing students fulfilled the following criteria: (a) 16 to 18 years old, both male and female; (b) taking the NCM course; (c) a pre-survey Perceived Stress Level (PSS) score of 16 or higher (indicating a high level of stress); and (d) not using any stress management techniques.

The Perceived Stress Scale (PSS) is a tool utilized to measure stress level based on the psychological perspective of stress that places emphasis on an individual's perception and evaluation of the potential harm posed by the stimuli. Interpretation was as follows:

Score	Interpretation
21 or higher	very high
16-20	high
12-15	average
8-11	low
0-7	very low

The investigators pretested the tool Perceived Stress Scale (PSS) and conducted the intervention Qi Gong among themselves prior to the study.

The actual gathering of data involved selecting 132 subjects who met the inclusion criteria from among the target population. They were divided into treatment and control groups. Both groups were asked to answer the PSS tool to determine their initial stress levels as pre-test (O₁). The treatment group was then made to watch the Qi Gong video prepared by the investigators. Qi Gong (also spelled as Ch'i Kung) is a system of healing and energy medicine largely based on the combination of breath control with stretching exercises. It is composed of a set of physical exercises combined with concentration. The subjects were asked to perform the steps on the said video with 5 investigators guiding them and demonstrating the said intervention together with the video. This procedure was implemented in the treatment group for four weeks.

On the other hand, the Control Group was not made to watch or perform the Qi Gong. The O₂ as post-test was given to both groups using the same PSS tool. Subjects in the treatment group had the post-test every week after the intervention while subjects in the control group took the post-test after four (4) weeks. The procedure was observed every Saturday for four weeks.

The sample size was 132 (66 participants per group), computed using Slovin's Formula. Data were analyzed using SPSS v14. The t-test was used to compare differences in mean scores of the stress level based on Perceived Stress Scale (PSS), pre- and post-survey within the treatment and control groups, and the mean score of the treatment group as compared to that of the control group before and after the series of interventions.

RESULTS

A total of 127 Level II nursing students participated in the study. The distribution is shown in Table 1. As shown in Table 2, both Treatment and Control groups had "very high" baseline stress mean scores. This was reduced to "high" in the Treatment group after Qi Gong. However, there was no statistically significant difference between the mean score of the treatment group versus the control group before and after the intervention ($p = 0.075$), implying that there was no significant decrease in the level of stress between the two groups.

Table 1. Distribution of the Respondents According to Group

	Treatment		Control		Total	
	n	%	n	%		
Age of Respondent	16	1	1.64	3	4.55	4
	17	38	62.30	39	59.09	77
	18	22	36.06	24	36.36	46
Total		61	100	66	100	127

Table 2. Mean Differences of Pre- and Post-Survey Stress Levels of the Control and Treatment Group

	Control		Treatment	
	Pre-Survey	Post-Survey	Pre-Survey	Post-Survey
Mean	21.65	21.00	22.00	19.75
N	66	66	61	61
Std. Deviation	3.768	3.907	3.088	3.906

DISCUSSION

Academic stress among college students has been a topic of interest for many years. College students, especially freshmen, are particularly prone to stress due to the transitional nature of college life. Many college students move away from home for the first time, which can force them to leave all previously learned support systems such as parents, siblings and high school friends and teachers. They develop entirely new social contacts and are expected to take responsibility for their own needs. They may have difficulty adjusting to more precise academic expectations and the need to learn to deal with individuals of differing culture, beliefs and practices.

Thus, stress may result from being separated from home for the first time, the transition from a personal to an impersonal academic environment, and the very structure of the academic experience at the college level. Significant changes in living conditions, the demands of the college academic environment, and the large change in social surroundings are just a few of the potential sources of stress for a college student.

College students face different amounts of stress due to different causes. Many aspects in college can contribute with its impact which may affect the physical and emotional health of the students. A student's life is composed of long hours of study, attending classes, meeting the deadlines and some social life. With all the responsibilities, the students tend to reduce or take out some of their leisure time. Time management together with academic and family pressure often increase the stress of the students. Having some stress management is a must for a student to face a hectic schedule and to become fully functional.

Some factors that aggravate the stress are academic demands include grade competition; lack of time or task management, the need to adapt to new learning environments; and the need to constantly self-regulate and to develop better thinking skills, including learning to use specific learning techniques⁷. Another factor that evokes stress is social adjustment, particularly adjusting to college life and separating from family and friends, as well as professors and the class environment, and concern about future careers⁸.

Qi Gong is a spiritual discipline that brings harmony and peace into one's life. In traditional Chinese medicine, Qi Gong is practiced as a stress managing method. This includes breathing, balance, coordination; concentration and visualization are parts of the method. Qi Gong can affect various functions where the nervous system and brain are involved with calmness, reduced breathing and pulse frequency. However, one speculation is that some of the effects are mediated through slow breathing, a key characteristic of this therapy. Controlling breathing has been shown to decrease heart rate and blood pressure⁹. It is suggested that reduced levels of stress may well correlate with higher productivity levels, less work related errors and a more relaxed workforce. Qi Gong exercise over even a short period may be able to significantly reduce symptoms of stress. The practice of this therapy may have increased participants' awareness of their overall health and well being so stimulating greater levels of physical activity or relaxation.

In healthy elderly men one hour of Qi-training significantly reduced the plasma concentration of cortisol and increased plasma concentrations of growth hormone and melatonin⁹. Some studies exploring Qi Gong effects focused on physiological changes or hormone levels that are related to stress, reported that 10 minutes of external Qi therapy could significantly reduce participants' anxiety, negative mood, and cortisol levels. Guo¹⁰ reported that the levels of catecholamine and cortisol in the Qi Gong group were significantly lower than those of the control group immediately after exposure to the stressor, but no difference was reported either at baseline or 1 hour after the stressor, suggesting that Qi Gong practice could suppress the reaction to mental and physical distress. Chan-Chuang¹¹ showed that Qi Gong attenuated the symptom distress and probably some part of the psychological distress of chemotherapy patients.

In summary, our study showed that Qi Gong as a stress management intervention was not able to significantly decrease the level of stress of undergraduate nursing students contrary to the results of previous study.¹⁰ This may be due to the fact that the intervention was done only for 10 minutes. A previous study required one hour of Qi-training to significantly reduce the plasma concentration of cortisol and increased plasma concentrations of growth hormones and melatonin which are hormones related to stress.¹²

As the data showed that the level II nursing students have a high level of stress, the investigators suggest that the nursing educators consider reviewing the work load given to their students every semester and to suggest to students to create a personal stress management routine to help them lower their stress levels. Although the decrease of stress levels between the treatment and control group was insignificant, data analysis showed that there was a trend to decrease in the level of stress within the treatment group. Therefore, the investigators suggest that further studies on the effects of Qi Gong therapy on the stress levels of undergraduate nursing students be made in the future and with an increase in the frequency and duration of Qi Gong intervention. Furthermore, the investigators would also like to suggest considering other stress management techniques along with Qi Gong therapy in a future study.

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Article 9

Spectrum of Demyelinating Diseases in a Tertiary Hospital from 2000-2010

Belinda Lioba L. Mesina, MD, Amado A. San Luis, MD, MSPH

Department of Clinical Neurosciences, Section of Neurology

ABSTRACT

Introduction/Objectives: In the absence of data to document and define the spectrum of demyelinating diseases in the country, this study aimed to describe the spectrum of demyelinating diseases of the central nervous system in adult patients admitted at the University of the East Ramon Magsaysay Memorial Hospital (UERM Hospital), from January 2000 to December 2010; and, to determine their clinical characteristics.

Methods: A descriptive, retrospective study was conducted, which included patients aged 18 years and above, whose final diagnosis was a demyelinating disease of the central nervous system admitted at UERM Hospital from January 2000 to December 2010.

Results: Fifty four Filipino patients were studied. A female preponderance was noted (4:1). The patient's age at the time of first admission ranged from 18 to 73 years, with a mean of 37.4 years. Age at onset of the disease ranged from 15 to 66 years, with a mean of 35.1 years. The relapsing-remitting form of multiple sclerosis (MS) was the most common clinical subtype (74%). The most common site of involvement was the optico-spinal areas. There were three cases of Acute Diffuse Demyelination (ADEM).

Conclusion/Recommendations: The spectrum of demyelinating diseases at UERM Hospital consisted of multiple sclerosis (MS), neuromyelitis optica (NMO), clinically isolated syndrome (CIS-optic and CIS-spinal) and acute disseminated encephalomyelitis (ADEM). There is a need to start a registry of demyelinating diseases in the Philippines to ascertain if indeed this is the pattern in the country.

KEY WORDS: Demyelinating diseases

INTRODUCTION

Owing to the diversity of their clinical picture, demyelinating diseases of the central nervous system have long been a challenge for most clinicians. Distinction between them depends on clinical history, paraclinical investigation, imaging and biological tests, and the exclusion of other etiologies, such as infectious, genetic, metabolic, and tumoral origins. The considerable overlap between some of these disorders may lead to diagnostic uncertainty.¹

Several diagnostic criteria for these diseases have been proposed through years of research, however, only a handful are widely recognized today. Wingerchuk² in 2006 and the International Panel on the Diagnosis of Multiple Sclerosis in 2010³, revised both the criteria for the diagnosis of neuromyelitis optica (NMO) or Devic's Disease, and the McDonald Criteria, for the diagnosis of Multiple Sclerosis (MS), respectively. Other MS variants lack actual criteria, and rely on clinical and histopathologic evidence as basis for diagnosis.

Prevalence studies on demyelinating diseases are limited to populations of MS. It affected approximately 350,000 individuals in the United States and 2.5 million worldwide, and in 2002, the overall prevalence estimate was 85 per 100,000 population.⁴ In Asia, MS is characterized by a lower prevalence, more frequent involvement of the optic nerve and spinal cord, especially in the Eastern region, and rare familial occurrence, as compared to those found in the West.^{5,6} In 2006, a systematic review of 105 articles on MS from 22 Asian countries, excluding the Philippines, showed the prevalence of MS to be highest in western Asia and the Middle East (i.e. Kuwait, Turkey, Jordan, Iraq, Israel, and Saudi Arabia), with a rate of 5–20 per 100,000 population, in comparison to that of the Eastern region, i.e. Japan, China, Hong Kong, Taiwan, Singapore, Thailand, Korea, and, Malaysia, at 0.8–2 per 100,000 population, and the Southern region, i.e. India, Pakistan, Bangladesh, Sri Lanka, Nepal, the Maldives and Bhutan, Iran, Myanmar, and Afghanistan, at 5 per 100,000 population.⁶ However, the papers used in this review were mainly hospital-based rather than population-based studies, limiting its scope.⁸

In 2008, the Registry of Asia Pacific Inflammatory Demyelination (RAPID) was launched, designed to identify the full spectrum of the demyelinating disease presentations, including atypical forms, and those associated with other systemic diseases or other disease markers and not linked to any form of therapy or medical intervention.⁷ It aimed to establish diagnostic criteria for MS and other demyelinating diseases, taking into consideration the unique presentation of the disease among people in the Asia-Pacific region.⁷ According to the proponents of the RAPID Study, the great difficulty was that the McDonald criteria were retrospectively derived from the analysis of a number of Western cohorts of MS, and inclusion of the full spectrum of demyelinating disease in these cohorts was highly improbable as the number of presentations of MS do not meet the Western criteria.⁷ In 2012, the RAPID Study reported 857 registered patients, the majority of whom were female (n=591). The most frequently registered diagnosis in the registry was MS with 651 patients (76%), followed by clinically isolated syndrome (CIS) with 68 patients (8%), neuromyelitis optica (NMO) with 42 patients (5%), acute disseminated encephalomyelitis (ADEM) with 13 patients (2%), and another 83 patients with various other diagnoses.⁸ Two other active MS registries, in Korea⁹ and Australia¹⁰, in the Asia-Pacific region were of note.

At present, no large population survey has been conducted to appraise the spectrum of demyelinating diseases of the central nervous system in our country. However, there were unpublished hospital based reviews that described MS alone. Large epidemiological studies are needed to study the incidence and prevalence of MS and other allied demyelinating diseases, and their natural disease course, in developing Asian countries⁶ like the Philippines.

To date, no large, multi-center survey has been conducted locally to document and define the spectrum of demyelinating diseases in the country. In this light, this study aimed to provide preliminary data for Filipinos, both MS and non-MS cases. Specifically, this study aimed to describe the spectrum of demyelinating diseases of the central nervous system in adult patients admitted at a tertiary hospital from January 2000 to December 2010 and to determine the clinical characteristics of patients diagnosed to have demyelinating diseases, for both MS and non-MS cases.

METHODS

A chart review of all Filipino patients, aged 18 years and above, with a final diagnosis of a demyelinating disease, admitted at a tertiary hospital from January 2000 to December 2010, was conducted. The inclusion criteria consisted of patients with a final diagnosis of a demyelinating disorder of the central nervous system upon discharge, or previously diagnosed cases re-admitted either due to further diagnostic procedures or relapse or complications of their disease, or other medical, surgical, or psychiatric conditions. Not included in the chart review were cases of hereditary demyelinating diseases or leukodystrophies, and cases of demyelinating diseases of the peripheral nervous system.

The search terms used were: demyelinating disease, multiple sclerosis, neuromyelitis optica, Devic's Disease, acute disseminated encephalomyelitis, postinfectious or postvaccine encephalomyelitis, transverse myelitis, and optic neuritis. The 2010 Revised McDonald Criteria³ was used as the basis for diagnosis of MS, while Wingerchuk's 2006² proposed criteria was used as the basis for the diagnosis of NMO. Other MS variants were diagnosed based on clinical presentation and laboratory findings.

RESULTS

Subject Characteristics

A total of 54 patients were included in the study. There were 43 females and only 11 males, a ratio of 4:1. The patient's age at the time of first admission ranged from 18 to 73 years, with a mean of 37.4 years. Age at onset of the disease ranged from 15 to 66 years, with a mean of 35.1. Majority (61.1%) of the patients had no known co-morbid conditions. The most common co-morbidity was hypertension, seen in 7 (13.0%) patients, followed by diabetes mellitus, hyperthyroidism, and migraine, each noted in 3 (5.5%) patients. One patient had a concomitant myasthenia gravis. Other co-morbid conditions noted were allergic rhinitis, breast mass, PTB exposure and head trauma. None of the patients had a family history of multiple sclerosis or any demyelinating disease of the central nervous system. These are shown in Table 1.

Table 1: Subject Characteristics

CHARACTERISITCS	n = 54	%
Gender		
Male	11	20.4
Female	43	79.6
Nationality		
Filipino	54	100
Mean Age, in years	37.4	
Range	18 - 73	
Mean Age at Diagnosis, in years	35.1	
Range	16 - 66	
With Co-morbid Conditions	25	46.2
Hypertension	7	
Diabetes Mellitus	3	
Hyperthyroidism	3	
Migraine	3	
Breast mass	2	
Allergic rhinitis	1	
PTB exposure	1	
Head trauma	1	
Myasthenia Gravis	1	

Clinic Diagnosis and Course

Using the recently revised McDonald Criteria for MS Diagnosis, majority of the patients diagnosed to have MS (62.9%) were classified as "Definite MS", while 12 cases (22.2%) were classified as "Possible MS". The remaining 3 cases (5.6%) were diagnosed cases of NMO, prior to their admission, and 5 cases (9.3%) were classified as "Not MS". These 5 were cases of ADEM (3), Postinfectious Demyelinating Disease (1), and Autoimmune Myelitis (1). Of the clinical subtypes, majority of the patients (25) had the Relapsing-Remitting form of MS (RRMS), 2 patients had the Primary Progressive (PPMS) form, 1 patient had the Chronic Progressive (CPMS) form, and 1 patient had Chronic Remitting MS (CRMS). For patients with RRMS, the average number of relapses was 2.08 per year. Seventeen (36.9%) of the 46 patients classified as either "Definite MS" or "Possible MS" presented as Clinically Isolated Syndromes (CIS). Of this subset, 11 patients had optic/retrobulbar neuritis, while 6 patients had transverse myelitis. These are illustrated in Figures 1 and 2.

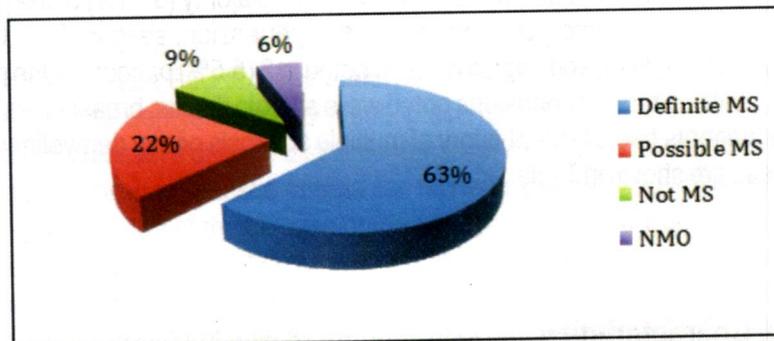


Figure 1: Diagnosis of Multiple Sclerosis and Neuromyelitis Optica

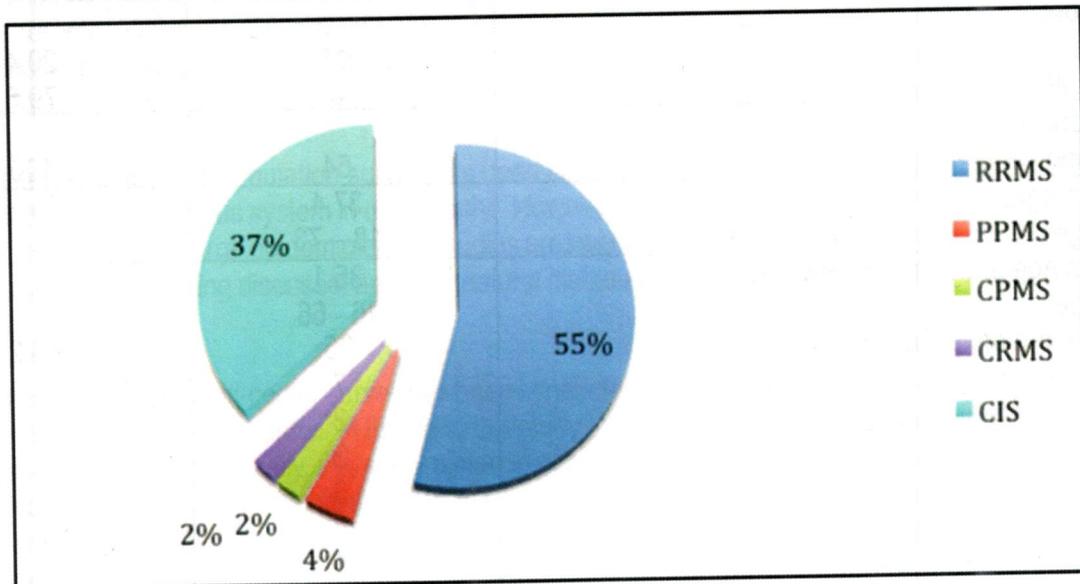


Figure 2: Clinical Subtypes of Multiple Sclerosis

As shown in Table 2, the most common presenting symptom was weakness, seen in 42.5% of cases. They either involved one, or both, upper and/or lower extremities, or generalized. This was followed by blurring or loss of vision in one or both eyes, seen in 25.9% of cases. Other presenting symptoms included numbness and paresthesias (18.5%), eye pain (5.6%), and diplopia (3.7%). One patient presented with focal seizures, and another presented with hand tremors. One patient had an intermittent fever with bilateral lower extremity weakness, while another had hiccups associated with blurring of vision.

Table 2: Presenting Symptoms

PRESENTING SYMPTOM	NO. OF PATIENTS
Weakness	23
Blurred/Loss of Vision	14
Numbness/paresthesias	10
Eye Pain	3
Diplopia	2
Fever	1
Seizure	1
Tremor	1
TOTAL	54

Subsequently, at some point along the course of their illness, 40.7% of the patients had a second documented attack. These attacks most commonly presented as weakness of the upper and or lower extremities at 40.9%, followed by documented optic neuritis at 27.2%, urinary incontinence at 13.6%, and numbness of the extremities at 9.1%. 22.2% of patients had a documented third attack, 14.8% had a 4th attack, and 11.1% had a 5th. For the subsequent attacks, the most common presenting symptoms were weakness and numbness of the extremities.

Diagnostics

The results of the patients' laboratory examinations and imaging studies were also reviewed. Magnetic resonance imaging (MRI) of the brain was done in 21 patients and were abnormal in 17 patients (85.7%). An MRI of the spine was also done in 17 patients, and results showed signal abnormalities in 16 patients (94.1%), mostly in the cervical and thoracic spinal segments. Eight cerebrospinal fluid samples were sent for determination of oligoclonal bands. Results were positive for 7 patients (87.5%). For evoked potentials, visual evoked responses were abnormal in 4 out of 9 tests done (44.4%), and one test (1.1%) was contaminated by artifacts. Somatosensory and brainstem auditory evoked responses were abnormal in 20% of patients (1 out of 5 tests) for both.

Treatment

All patients were treated with high dose corticosteroids, with a short course intravenous infusion of methylprednisolone at 500 mg–1000 mg per day, for 3–5 days, followed by oral therapy with prednisone, starting at 1 mg per kilogram, tapered off over a period of 1 month. The patients were noted to improve clinically after receiving the said treatment. One patient was additionally treated with interferon-beta and another patient was additionally treated with azathioprine.

Complications and Prognosis

For patients with moderate to severe disabilities, the most common complications were bladder dysfunction, urinary tract infections, sacral decubitus ulcers secondary to immobility, and aspiration pneumonia. One patient was readmitted because of depression.

Information regarding the patient's present status was available only for 20 patients. The average disease duration for these patients was 4.8 years. One patient had repeated readmissions due to recurrent urinary tract infections and sepsis, and died during the first year of her illness. Functional status of the remaining 19 patients were classified using the Kurtzke Expanded Disability Status Score (EDSS).¹¹ Of these patients, 7 had normal neurologic examinations, and were fully functional (EDSS = 0–0.5), 5 had minor disabilities (EDSS 1–2), 3 had moderate disabilities (EDSS = 5–6), and 4 had major disabilities, and were wheel-chair bound.

DISCUSSION

Data from this present study were consistent with findings from previously published articles. The female to male ratio of 4:1 is comparable to the 4.5:1 ratio reported by Hung in 1982.¹² This female preponderance was also noted in more current studies.⁷ The rare occurrence of a family history of MS or demyelinating disease has also been noted by several authors.⁵

Opticospinal involvement was shown to be prevalent in this present study. More than half of the patients included in this study presented with symptoms attributable to the affectation of the optic nerve, i.e. blurring or loss of vision, and the spinal cord, i.e. weakness, numbness, and paresthesias consistent with the study done in Korea wherein typical clinical features of MS presented among these patients including a frequent relapsing-remitting course, and selective clinical involvement of both the optic nerve and the spinal cord.¹³ Lesions seen in the cranial and spinal MRI support these findings. However, no aquaporin P4 (AQP4) antibody determination nor a NMO-IgG level to rule in NMO, were available for any of the patients suspected to have this variant. Whether these were cases of the "Asian opticospinal MS" or just a variant of NMO remained to be an area of uncertainty.

Short courses of high-dose corticosteroids have been routinely used to treat acute MS relapses for many years. The first therapeutic advance in this area began with the use of adrenocorticotrophic hormone (ACTH) to stimulate the synthesis of corticosteroids.¹⁴ A number of studies support the concept that steroids accelerate recovery.^{15, 16, 17, 18} All of the patients in the study received high-dose corticosteroids as first-line treatment.

Complications and prognosis of patients with MS and other demyelinating diseases of the central nervous system depend on the frequency of the recurrence of the attacks, and their severity. As noted in another retrospective study done in Singapore, recurrent myelopathy not unexpectedly causes urological complications frequently⁵ where one third of patients needed permanent indwelling catheters or clean intermittent catheterization for prolonged periods.⁵ The low incidence of depression in the present study may be partly due to under-recognition or under-reporting.⁵

In summary, our study described the clinical characteristics of demyelinating diseases of the central nervous system in a tertiary hospital in the Philippines. Female preponderance, optico-spinal involvement, favourable response to steroid treatment, and the relapsing-remitting form of MS, were consistent with the findings from studies done in other Asian countries. However, this present study was limited to admitted patients, and failed to consider cases of MS and other allied demyelinating diseases diagnosed and treated in the outpatient setting. Consequently, large population studies are recommended to widen the scope of such studies in the future, utilizing an institutionalized registry to standardize data collection in the country.

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Article 10

The Use of Human Placenta Extract in the Promotion of Wound Healing: An Experimental Study in Rabbits

Fremont John Galan Base, MD; Lutgardo Caparas, MD, FPAPRAS; Jennifer Nailles, MD, MSPH

Department of Surgery

ABSTRACT

Introduction/Objectives: A primary concern in the post-operative period is wound healing and with it, the rate at which wound healing can be achieved. Many have comprehensively pursued efforts to come up with treatment modalities to bring about the acceleration of wound healing and one of these is human placenta extract. This study aimed to determine whether or not human placenta extract accelerated wound healing and produce a cosmetically acceptable scar as well.

Methods: Twenty healthy male albino New Zealand rabbits weighing 1.8 to 2kgs were used in this study. Each rabbit had two wounds 2 x 2 cm prepared on each flank. One side was painted with human placenta extract (experimental group) and the contralateral side, with saline (control group) daily for 7 to 10 days post-operatively. The wound was inspected daily for granulation tissue formation. Tissue samples were obtained on the 10th post-operative day and examined for cellular infiltration, collagen deposition and arrangement.

Results: Fourteen out of 20 (70%) wounds in the experimental group had complete healing on the 7th post-operative day while 14/20 (70%) wounds in the control group had only moderate healing and was statistically significant. All of the wounds in the experimental group showed granulation tissue formation on the 6th post-operative day while the same percentage was achieved on the 8th day in the control group, which is statistically significant. Nineteen out of 20 (95%) wounds in the control group had mild cellular infiltration while 14/20 (70%) wounds in the experimental group had mild cellular infiltration with statistical significance. Fourteen out of 20 (70%) wounds in the experimental group had moderate collagen deposition on the 10th post-operative day while 12/20 (60%) wounds in the control group had mild deposition, also statistically significant.

Conclusion: Human placenta extract made an impact on the extent and rate of granulation tissue deposition compared to saline-treated wounds in rabbits. Likewise, the study showed that it resulted in less inflammatory reaction but more collagen deposition in a more parallel arrangement.

KEY WORDS: Human placenta extract, wound healing, rabbits

INTRODUCTION

The practice of surgery is closely associated with wounds, and with the more detailed understanding of the repair process and their regulation, the surgeon's role in wound healing has gradually progressed into an active one through pharmacologic treatment. Various studies aimed toward improvement of the healing process have been conducted. However, the search for a substance that would result in the accelerated process of wound healing in tissues goes on. One of these is human placenta extract which has been used in Japan since the 1950s mainly for liver disease and menopause.

Recently, its application extended to a myriad of medical problems including wound healing. A study using human placental extract for wound healing was done as early as 2001. Biswas and others showed that the use of placental extract in rats resulted in a significant decrease in wound size, wound index and lowering in the number of days for complete healing.² Shukla in 2004, made a clinical trial to determine the role of placental extract in the treatment of chronic non-healing wounds. End points included wound size and rate of epithelialization. Although most patients dropped out, it however showed that more than 67% in the treatment group showed more than 50% epithelialization over an 8-week period.³

The wound healing capacity of human placenta extract has been attributed to the presence several growth factors⁴ that promote angiogenesis, NADPH⁵ that hastens anabolic reactions and Fibronectin Type III⁶, an important component of the extracellular matrix that help bind collagen and fibrin in the wound.

There have been several other studies that show the favorable wound healing capacity of human placenta extract. However, despite its commercial availability and relatively inexpensive cost, it has not gained recognition in the treatment of wounds in the local setting. The purpose of this study, therefore, was to compare human placenta extract with saline with regards to the degree of healing, the length of time it takes for granulation tissue to form and the inflammatory reaction and collagen deposition of the healed wounds.

METHODS

This study used human placenta extract produced by Japan Bioproducts Industries Co., Ltd.⁷ All animal experiments were carried out according to the Guidelines for Care and Use of Laboratory Animals.⁸ Twenty healthy male albino New Zealand rabbits (*Oryctolagus cuniculus*) 10-12 months old, weighing 1.8 to 2.0 kg were used. Each rabbit had two separate wounds on each flank: one side for application of human placenta extract with the contralateral side for application of sterile saline solution. Randomization of site for treatment in each rabbit was done by an assistant. Plastic bands were then placed on hind legs of each rabbit, one on the left and another on the right. Each band was labeled with a unique identifying number that was coded; a corresponding unique number was assigned to each of the flank site subsequently treated with human placenta extract while a different set of unique numbers was assigned to the remaining contralateral flank sites. The latter was subsequently treated with sterile saline solution. The codes were kept secret by the assistant, who was later responsible for breaking the same codes during the collation of data at the termination of the study.

All rabbits underwent a procedure under aseptic conditions after induction of general anesthesia using the recommended dose of 3mg/kg of Zoletil (Tiletamine HCl 125mg + Zolazepam HCl 125mg) for rabbits.⁹ The same surgeon blinded to the treatment group performed all the operations. The flanks were shaved and prepared using aqueous benzalkonium chloride. A 2.0cm x 2.0 cm square full skin thickness wound was created on each flank (Figure 1) using a sterile blade 15. The wound edges were scraped gently until bleeding was noted. The raw areas were left open.



Figure 1. Rabbit with a 2x2cm wound on the left flank.

Immediately after the procedure, human placenta extract was applied by another assistant to one of the two wounds selected randomly as previously described. The wounds were categorized under Group I: Human Placenta Extract Treated or Experimental Group. The other wound on the contralateral flank was subsequently painted with sterile saline solution. These wounds were considered under Group II: Human Placenta Extract-Free or Control Group. Treatment was continued daily thereafter for the next 7 days, the average time length of time for full thickness wounds to heal in rabbits.¹⁰ However, if granulation tissue failed to form on the 7th day, treatment with human placenta extract and/or saline was continued until the 10th post-operative day. The wounds were examined daily by another observer blinded to the study, taking note of the number of post-operative days when the first sign of granulation tissue formation and/or the appearance of a new epithelial layer was first observed.

The degree of wound healing was then determined using a scoring system designed by Krasner.¹¹ The following scoring system based on granulation tissue formation was followed: characteristic of granulation score range from 0 to 4 points; extent of deposition of granulation tissue score range from 0 – 4 points; and site of deposition of granulation tissue score range from 0 to 2 points. The scores under each category were added to come up with a wound healing score. A score of zero (0) corresponded to an assessment of “no wound healing”; 2–4 points was considered “minimal wound healing”; 5–7 points was “moderate wound healing”; and 8–10 points was considered “complete wound healing”. This system was used to standardize the evaluation of wound healing. By this method, the final granulation tissue formation score reflected the degree of wound healing, thereby enabled the author to compare the effect of human placenta extract on the promotion of wound healing throughout the experiment.

On the 10th post-operative day, skin tissue incorporating each of the incision sites were harvested under the same aseptic technique with the study animals under general anesthesia. Tissue samples were separately fixed with 10% formaldehyde and embedded in paraffin. Cross sections were obtained from each incision and subsequently stained with Hematoxylin and Eosin. The following parameters were evaluated and scored based on a modification of a system designed by Filmar: number of polymorphonuclear leukocytes, lymphocytes and histiocytes; giant cells; and the amount of collagen.¹² This method enabled the author to determine and subsequently compare the degree of inflammatory reaction between the two groups. Furthermore, assessment of the quality of healed wound that finally resulted among the two study populations was based on a standardized scoring system designed by Calaor.¹³ The histologic composition of wound tissue samples were scored based on the number of cellular infiltrates per section. The same point system was followed for assessment of the amount of collagen fiber deposition. The author was able to compare the quality of wound repair between the two groups. All tissue samples were examined and scored by the same pathologist blinded to the study.

Data gathered were analyzed using the Mann-Whitney U-test and t-test SPSS Predictive Analysis software version 14. All p-values less than or equal to 0.05 were considered significant.

RESULTS

Table 1 shows the frequency distribution of the groups based on wound healing scores. Human placenta extract treated wounds had “complete healing” in 14/20 (70%) cases. Five (25%) wounds had “moderate healing” while 1 (5%) had “minimal healing.” None of the wounds had “no healing” on the 7th post-operative day. For the control group, only 1 (5%) had “complete healing”; “moderate healing” was seen in 14/20 (70%) wounds. Four (20%) wounds had “minimal healing” and at 1 (5%) had “no healing” on the 7th post-operative day.

Table 1: Frequency distribution of human placenta extract treated wounds and human placenta extract free wounds bases on wound healing scores (7th postoperative day).

Wound Healing	Experimental Group (n=20)		Control Group (n=20)	
	Number	Percent	Number	Percent
No Healing	0	0	1	5
Minimal Healing	1	5	4	20
Moderate Healing	5	25	14	70
Complete Healing	14	70	1	5
TOTAL	20	100	20	100

The mean healing score for the experimental group was 27.83 (4-9) compared to 13.18 (0-8) for the control. Using the Mann-Whitney U-test, the difference in the mean rank between the human placenta extract treated group and the human placenta extract free group was statistically significant ($p < 0.0001$).

All 20 wounds had granulation tissue formation by the 6th post-operative day. In the control group, treatment was extended up to the 10th post-operative day in one wound and subsequently showed initial granulation tissue formation on the 8th post-operative day. Furthermore, most wounds exhibited initial granulation tissue formation during the 2nd and 3rd post-operative days and as early as the 1st post-operative day, granulation was already noted in the human placenta extract treated wounds. In the control group, most wounds showed initial granulation tissue formation on the 3rd and 4th post-operative days. The mean time for initial granulation tissue formation in the human placenta extract treated group was 2.95 ± 1.356 days as compared to 4.45 ± 1.669 for the control. The difference between the two groups was statistically significant ($p = 0.0031$, Mann Whitney U test). Figure 2 illustrates the thick granulation tissue in a wound belonging to a rabbit in the experimental group.



Figure 2. Thick layer of granulation tissue covering the entire incision in wound of a rabbit in the human placenta extract treated group on the 4th post-operative day. Also noted is presence of significant wound contraction.

Table 2 shows the distribution of human placenta extract treated wounds and placenta extract free wounds as to the degree of inflammatory reaction after 10 post-operative days. Both groups had either "mild inflammation" or "no inflammation." However, 19/20 (95%) wounds in the control group had "mild inflammation" as compared to only 14 (70%) in the control. Comparing the cellular infiltration scores between human placenta extract treatment group and control, results showed the mean score for the experimental group to be 14.60, significantly lower than that in the control of 26.40 ($p = 0.001$, Mann Whitney U test). There was, therefore, less inflammation in the human placenta extract treated group. This is further illustrated in **Figure 3**.

Table 2: Frequency Distribution According to Cellular Infiltration Scores

Inflammatory Reaction	Experimental Group (n=20)		Control Group (n=20)	
	Number	Percent	Number	Percent
No Inflammation	6	30	1	5
Mild Inflammation	14	70	19	95
Moderate Inflammation	0	0	0	0
Severe Inflammation	0	0	0	0

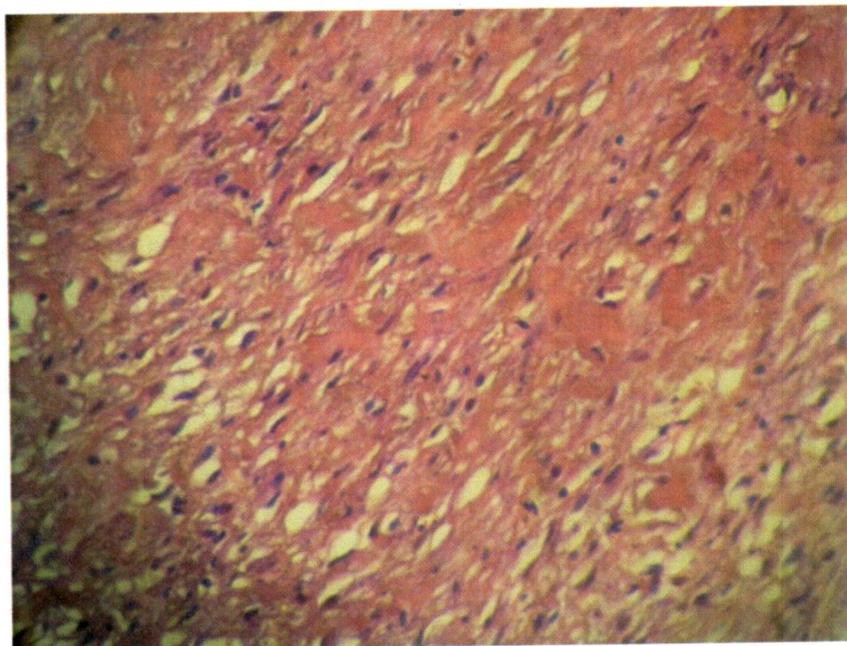


Figure 3. This is am human placenta extract wound tissue taken on the 10th post-operative day. It shows mild inflammatory infiltration. However collagen deposition was noted to be abundant and arranged in a more parallel fashion.

Table 3 shows the frequency distribution of human placenta extract treated wounds and human placenta extract free wounds as to the amount of collagen fiber deposits detected in the healed tissues on the 10th post-operative day. Fourteen of the 20 (70%) wounds in the treated group had "moderate collagen deposits." Likewise, 5/20 (25%) had "abundant deposits" while 1 (5%) had "mild deposit." In contrast, for the control, majority (60%) of the wounds had only "mild collagen deposits" and 3 (15%) wounds had "no deposits." The mean collagen deposition score in the human placenta extract treated group was 27.73 as compared to 13.27 in the control; this difference was statistically significant ($p < 0.0001$, Mann-Whitney U test).

Table 3: Frequency Distribution According to Collagen Deposition Scores.

Collagen Deposition	Experimental Group (n=20)		Control Group (n=20)	
	Number	Percent	Number	Percent
No deposit	0	0	3	15
Mild deposit	1	5	12	60
Moderate deposit	14	70	4	20
Abundant deposit	5	25	1	5

DISCUSSION

A primary concern in the post-operative period is wound healing and with it, the rate at which wound healing can be achieved. Normally, it takes at least 7 days for granulation tissue formation and collagen deposition in simple wounds to occur.¹⁴ It takes longer for some patients with concomitant medical problems. Some patients end up with chronic non-healing wounds. In view of this, investigators have comprehensively pursued efforts to come up with treatment modalities, some subject to randomized controlled trials, to bring about the acceleration of wound healing. These include hyperbaric oxygen therapy, phototherapy, growth factors and nutrient supplementation. More novel approaches that have arisen include the use of immunoglobulins, chitosan, hyaluronic acid and placenta extract.¹⁵

There have been several studies that used human placenta extract for wound healing. They showed the efficacy of human placenta extract in accelerating wound healing in experimental animals and humans. However, it has not gained widespread acceptance in the local setting. In this study, human placenta extract showed greater propensity for granulation tissue to form in the treated wounds in rabbits. This further supported the studies made by Biswas² and Shukla³ in 2001 and 2004, respectively. It showed that human placenta extract was significantly better compared to saline in promoting granulation tissue formation.¹ This is also consistent with a study by Hong (2010) which showed that human placenta extract accelerated wound coverage by granulation tissue.¹⁶ This study further validated this study's results by showing that there is a significant difference in the length of time it takes for granulation tissue to form with the use of human placenta extract compared to that of saline.

Very little is said about the beneficial effects of human placenta extract in terms of inflammatory reaction and collagen deposition. This study showed that there was significantly less inflammatory reaction and more collagen deposition with the use of human placenta extract in wounds in rabbits. At the same time, the use of human placenta extract resulted in a more parallel arrangement of new collagen. This is noteworthy because several studies have shown that scar-less fetal wound healing reflects the organization of collagen, not the absence of collagen in the fetal wound matrix.¹⁷

In summary, this study showed that the use of human placenta extract in the treatment of wounds in rabbits promoted wound healing. It revealed that granulation tissue formation is promoted and accelerated. At the same time, there is less inflammatory reaction with greater collagen deposition. The author recommends that future studies be designed to address the use of human placenta extract, its acceptability and safety in human subjects and most specifically, in surgical patients to confirm its usefulness in surgical practice. The efficacy of human placenta extract compared to other standard medications that promote wound healing can also be designed. Furthermore, trials on the optimum preparation, dosage, frequency of application of human placenta extract can be the focus of future studies.

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2. Krugman S, Lacy LR, et al. Viral hepatitis type B. *N Engl J Med.* 1979; 300:101-106.

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2. Selwyn AP, Braunwald E. Ischemic Heart Disease. In: Braunwald E, Isselbacher KJ, Petersdorf RG, editors. Harrison's Principles of Internal Medicine. New York: McGraw-Hill, 1987: 975-982.

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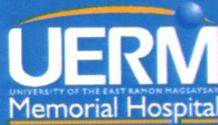
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Research Institute for Health Sciences
2/F, Jose M. Cuyegkeng Building
University of the East Ramon Magsaysay Memorial Medical Center
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